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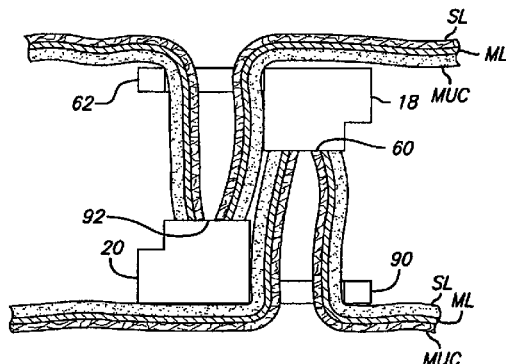
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- (57) **ABSTRACT**

A system for tissue approximation and fixation is described herein. A device is advanced in a minimally invasive manner within a patient's body to create one or several divisions or plications within a hollow body organ. The system comprises a stapler assembly having a tissue acquisition member and a tissue fixation member. The stapler assembly approximates tissue from within the hollow body organ with the acquisition member and then affixes the approximated tissue with the fixation member. In one method, the system can be used as a secondary procedure to reduce the size of a stoma within the hollow body organ.

**18 Claims, 62 Drawing Sheets**



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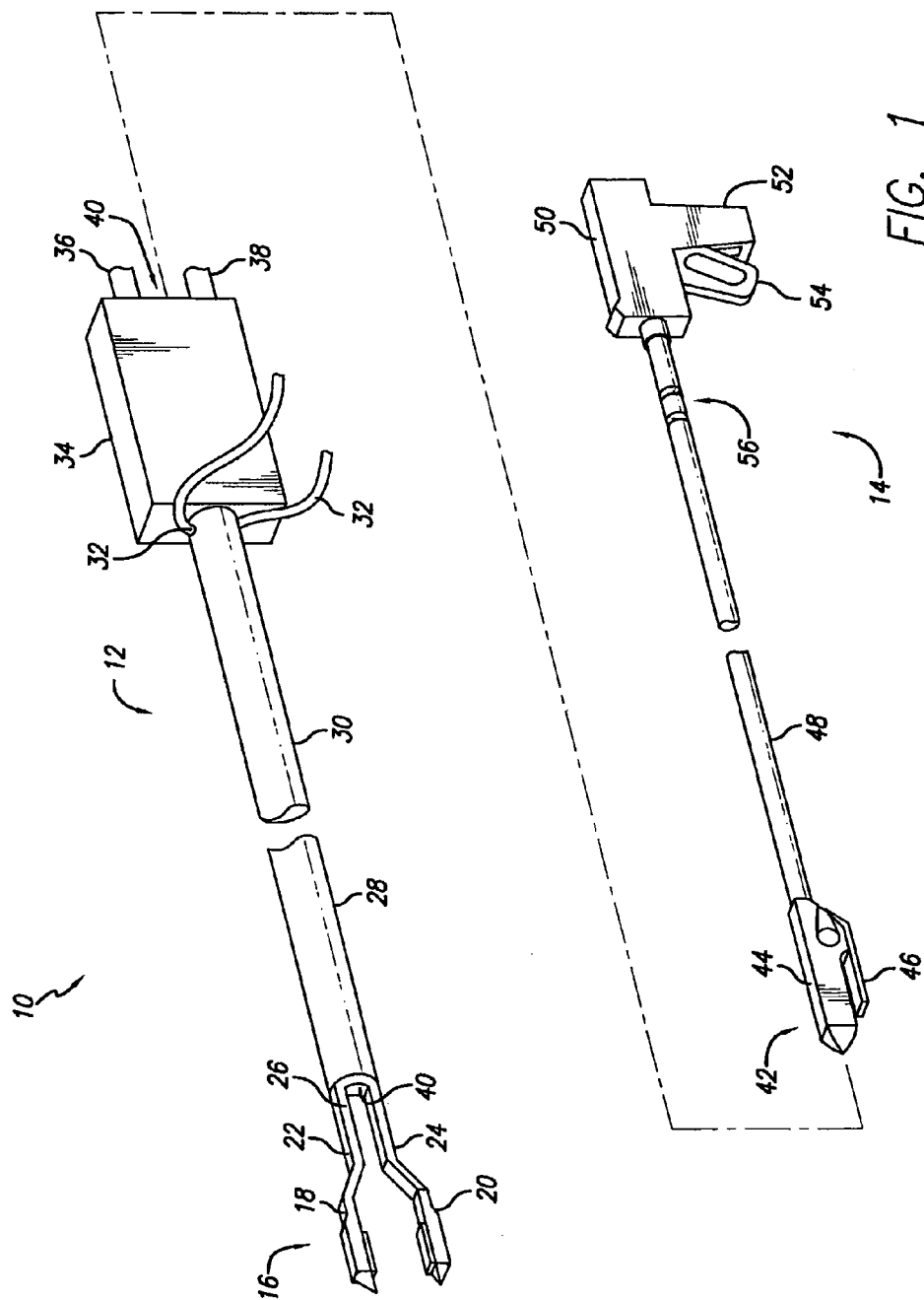
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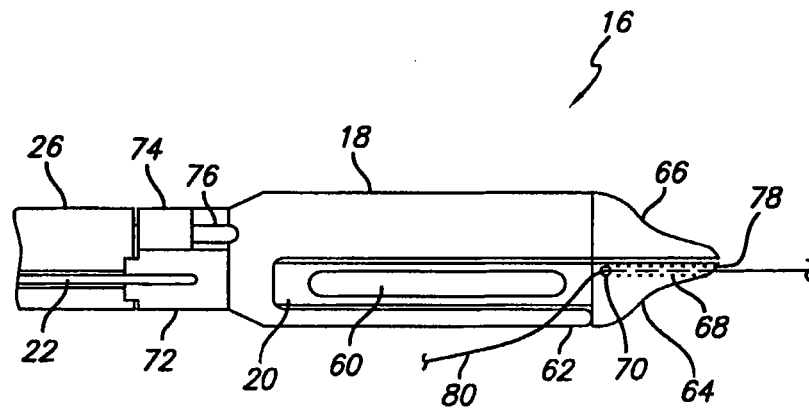


FIG. 2A

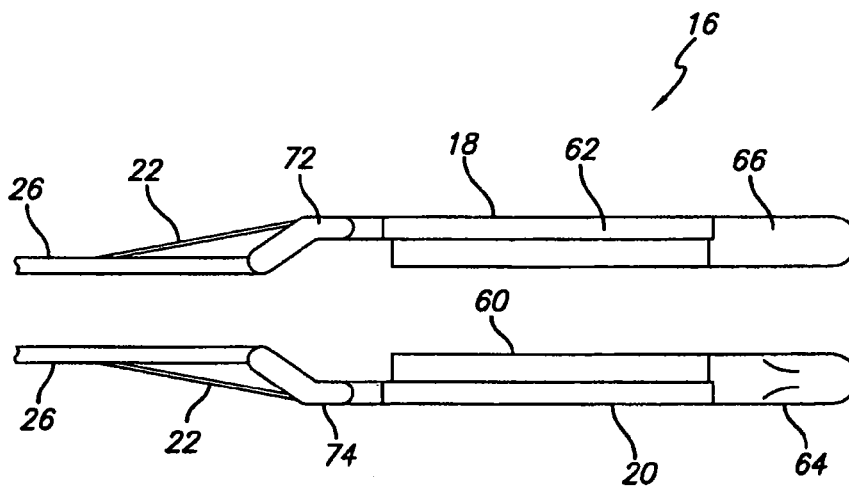


FIG. 2B

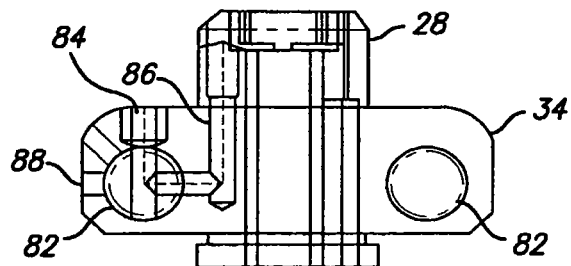


FIG. 2C

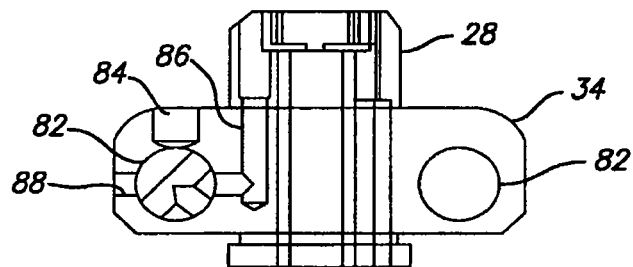


FIG. 2D

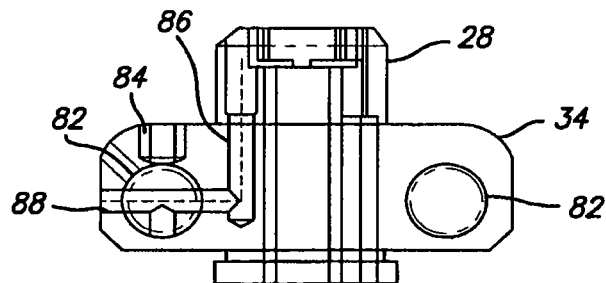


FIG. 2E



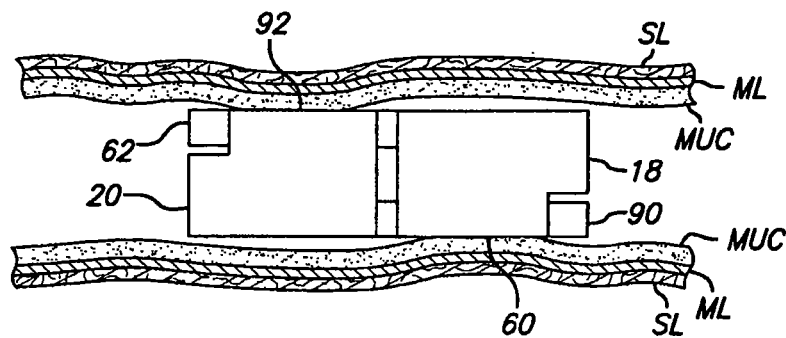


FIG. 3A

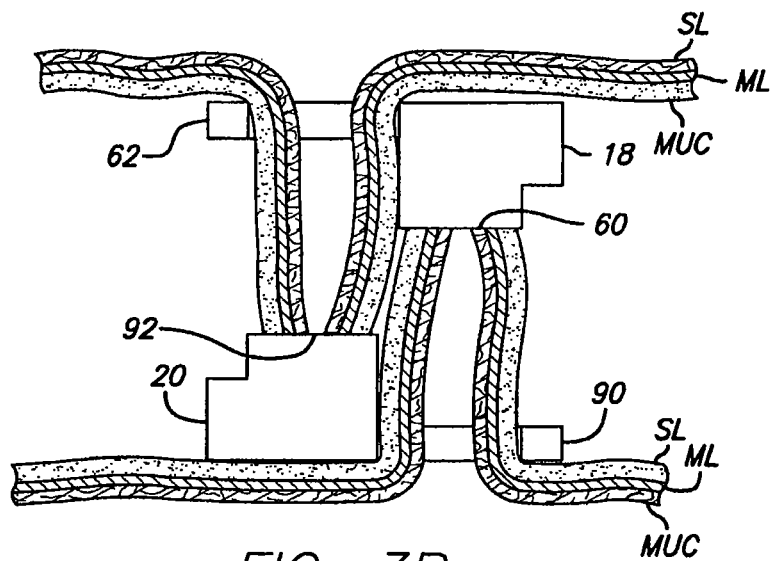


FIG. 3B

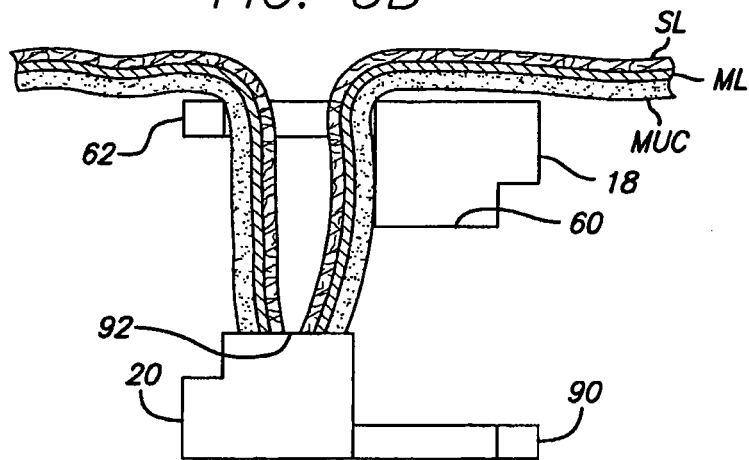


FIG. 3C

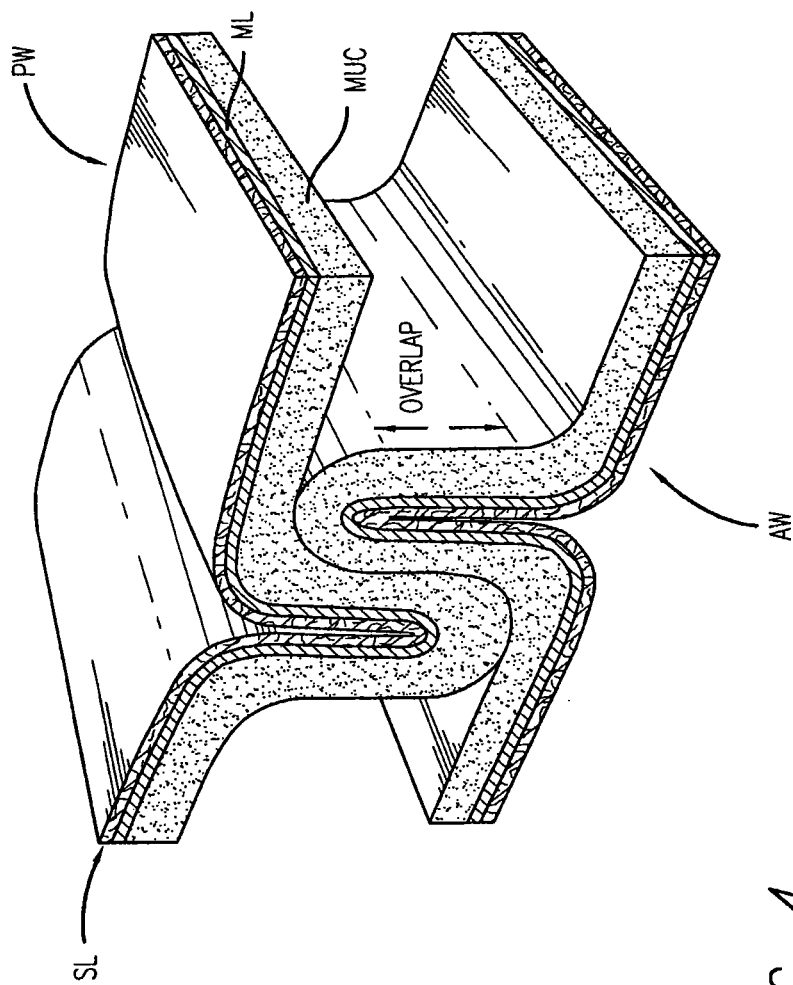


FIG. 4

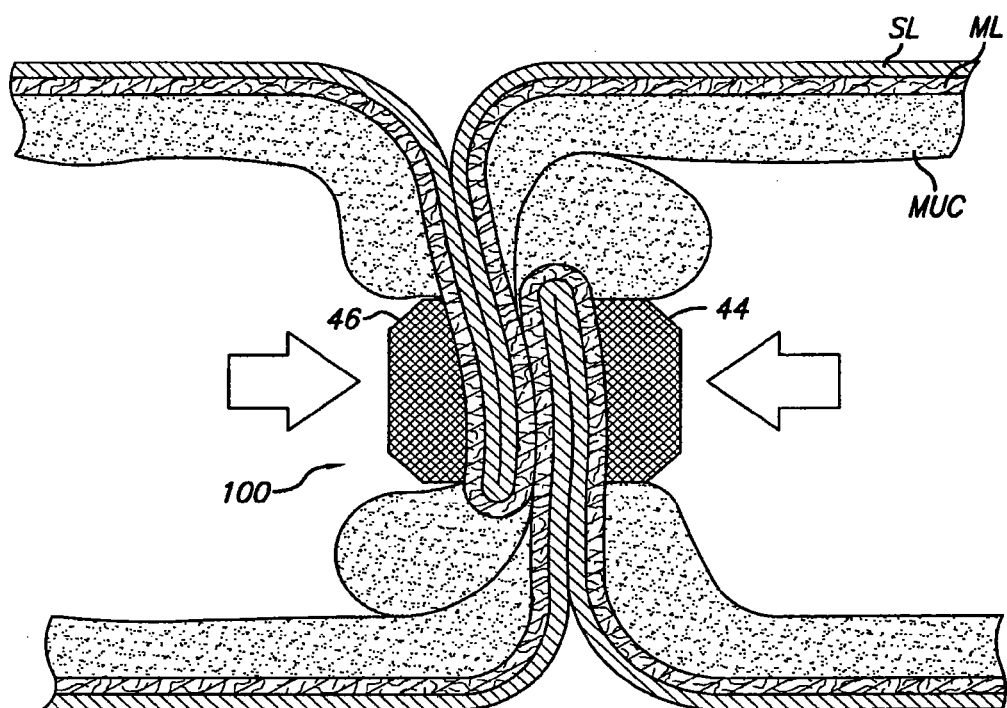


FIG. 5

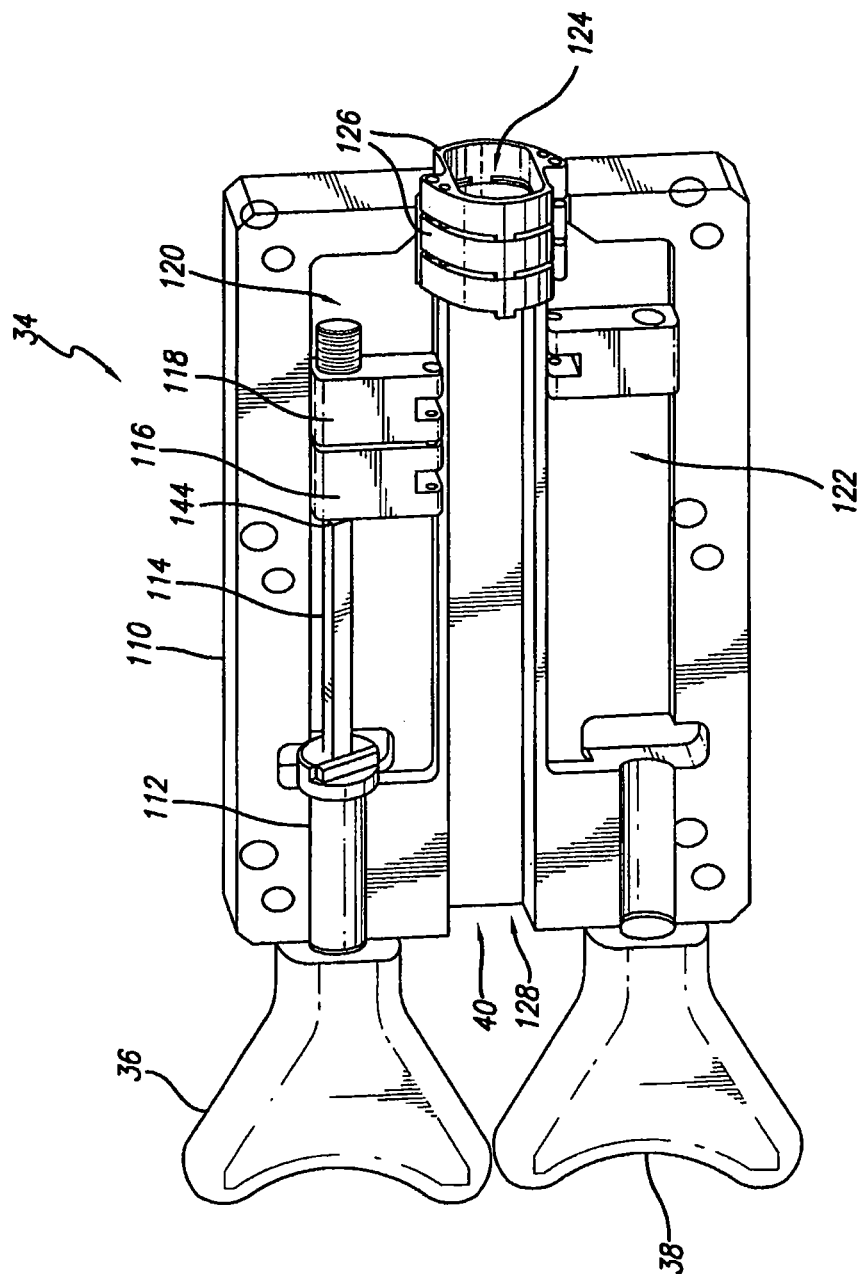


FIG. 6A

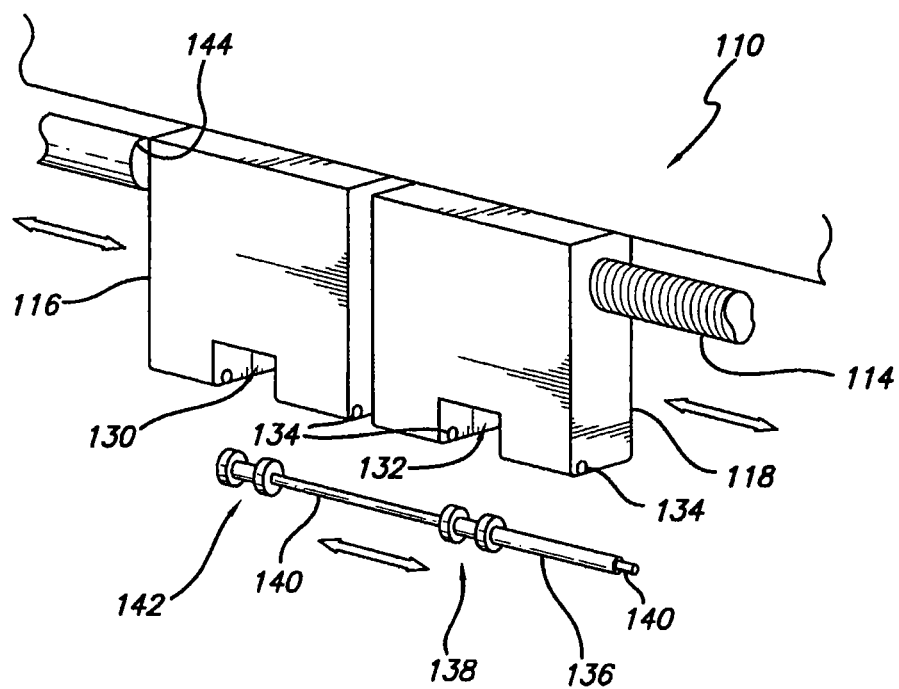


FIG. 6B

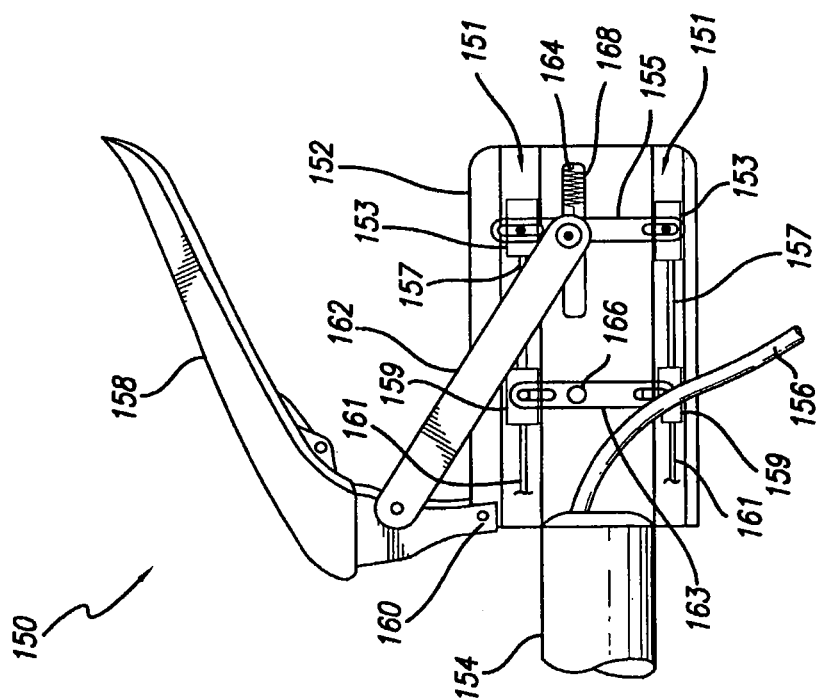


FIG. 7

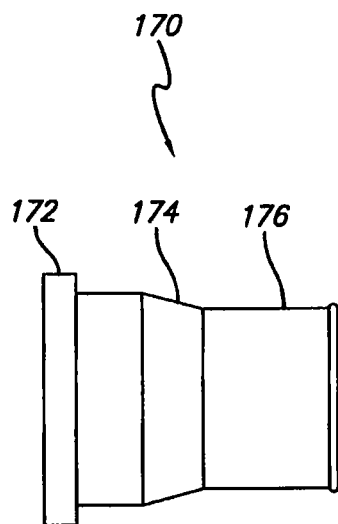


FIG. 8A

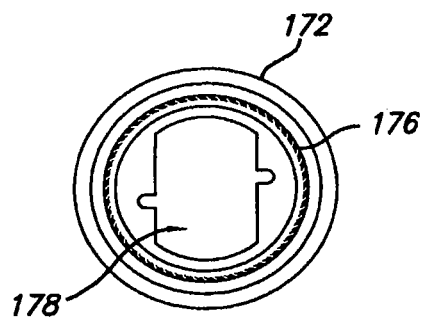


FIG. 8B

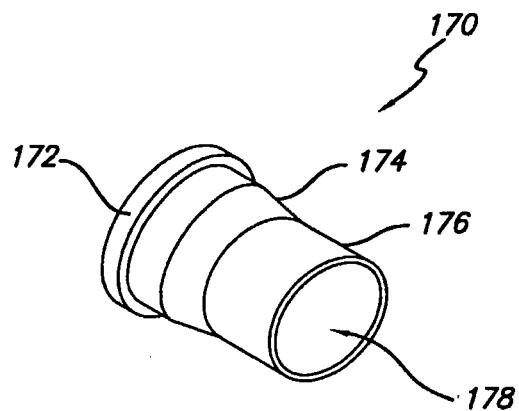


FIG. 8C

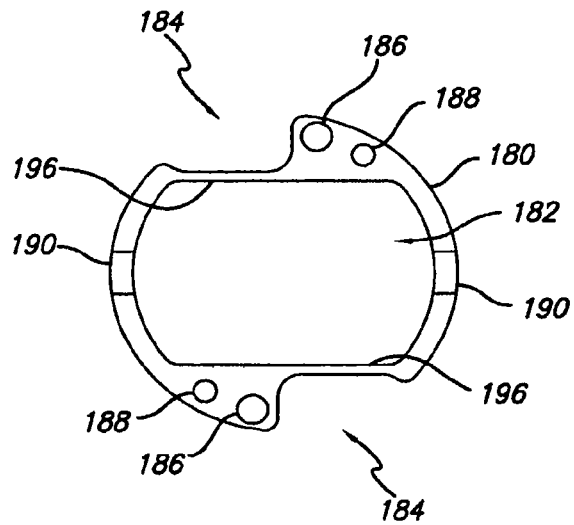


FIG. 9A

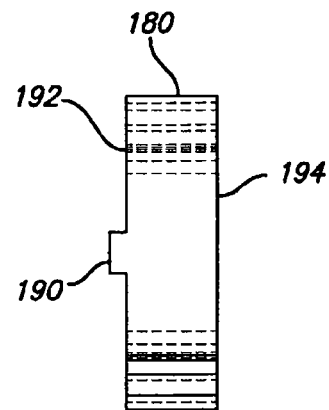


FIG. 9B

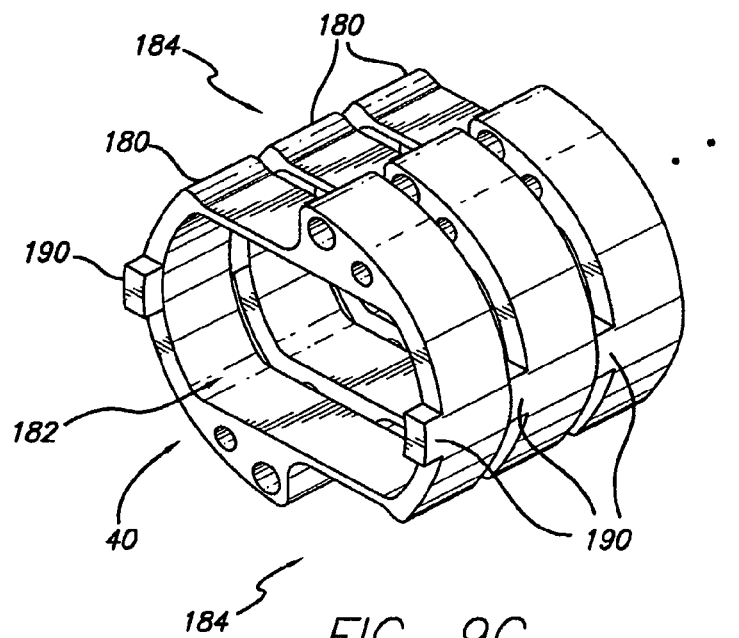


FIG. 9C



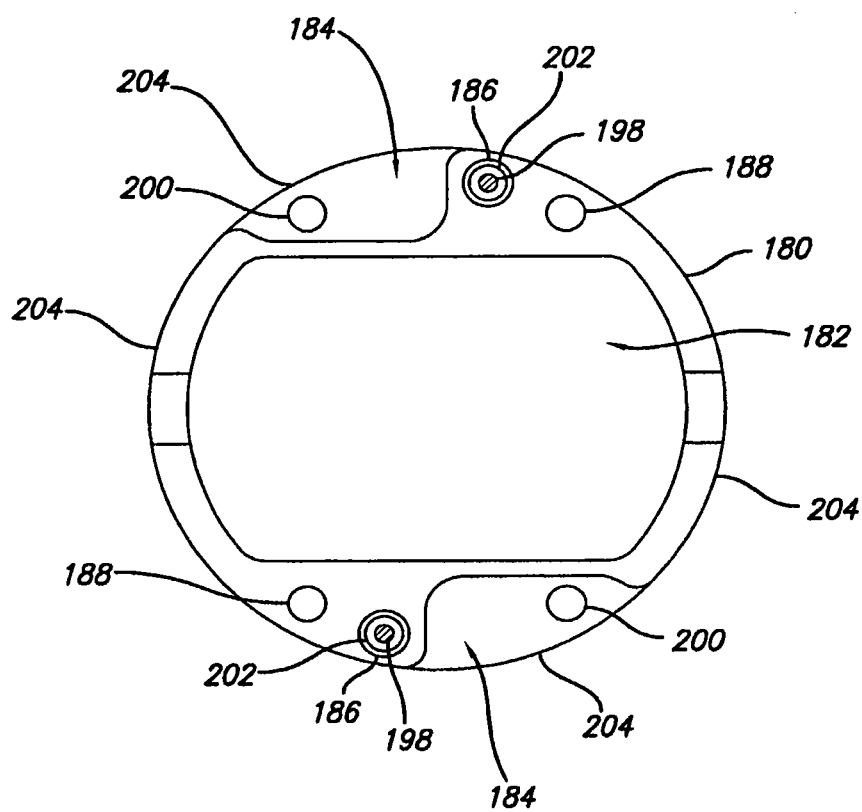


FIG. 9D

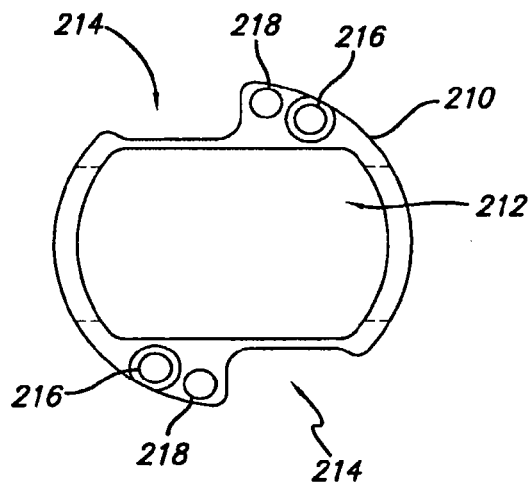


FIG. 10A

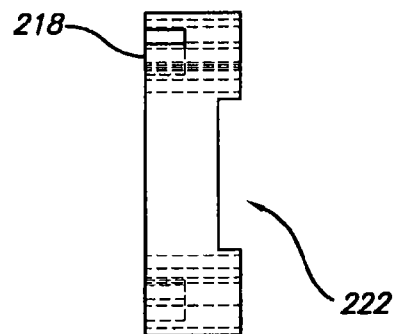


FIG. 10B

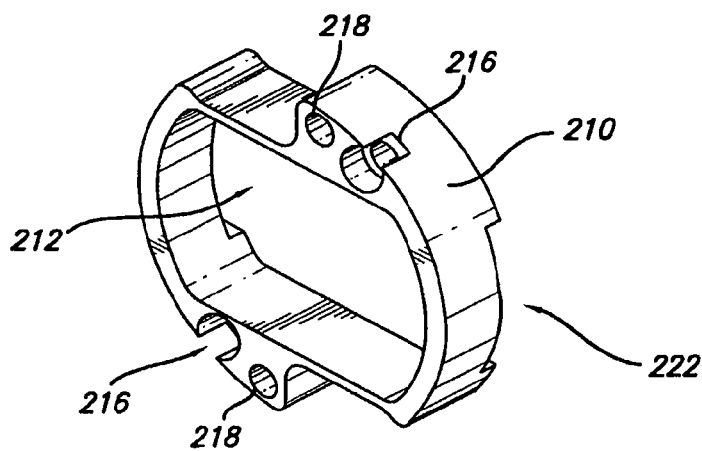


FIG. 10C

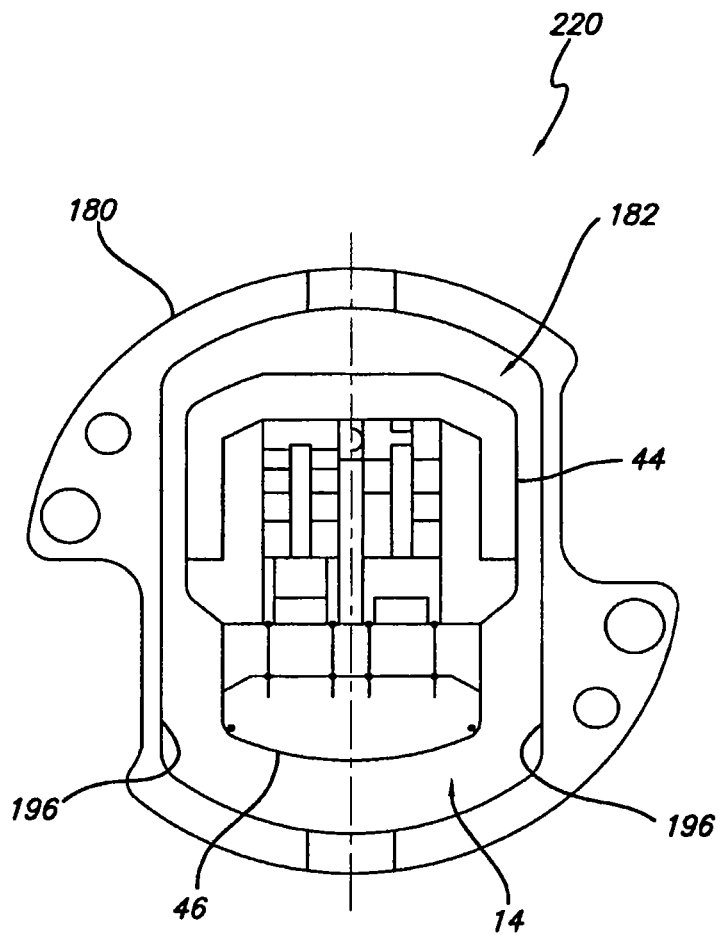


FIG. 11

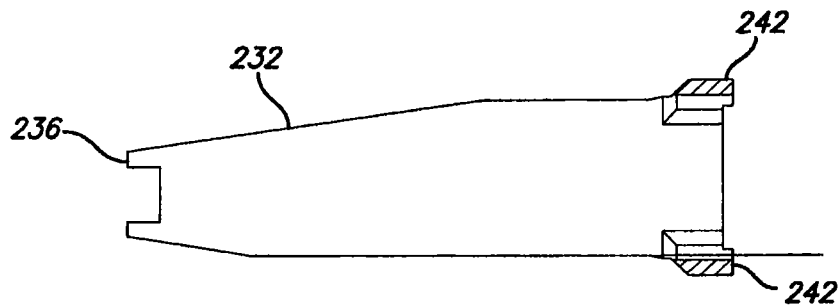


FIG. 12B

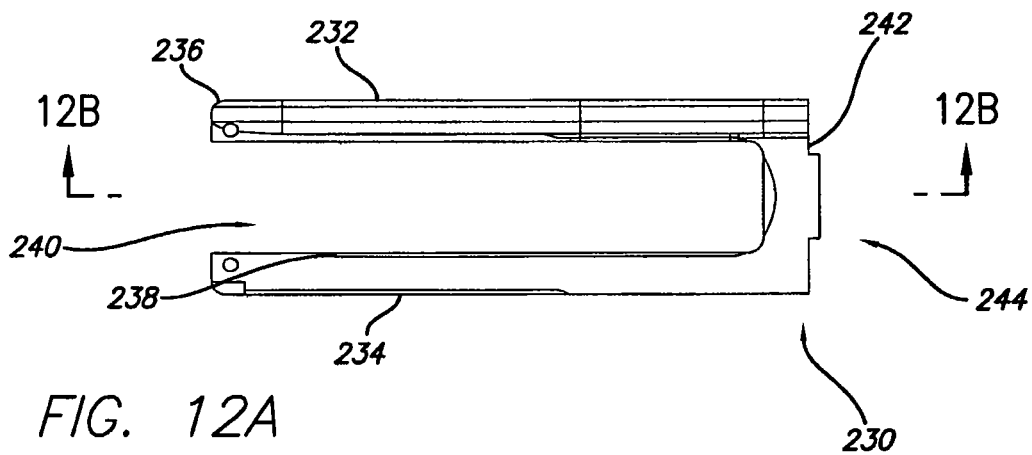


FIG. 12A

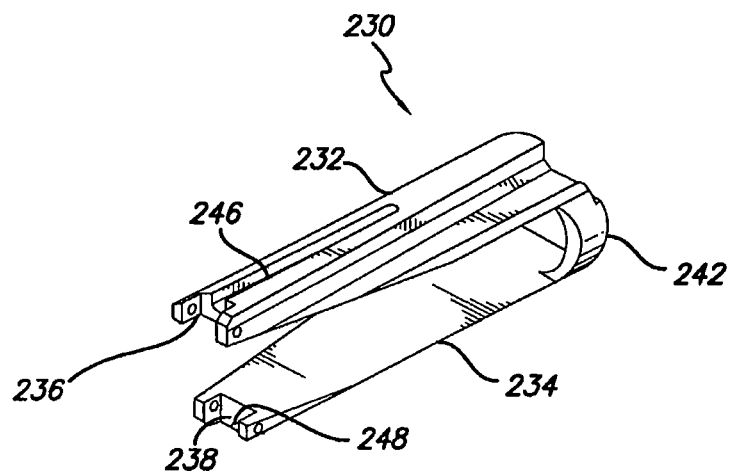


FIG. 12C

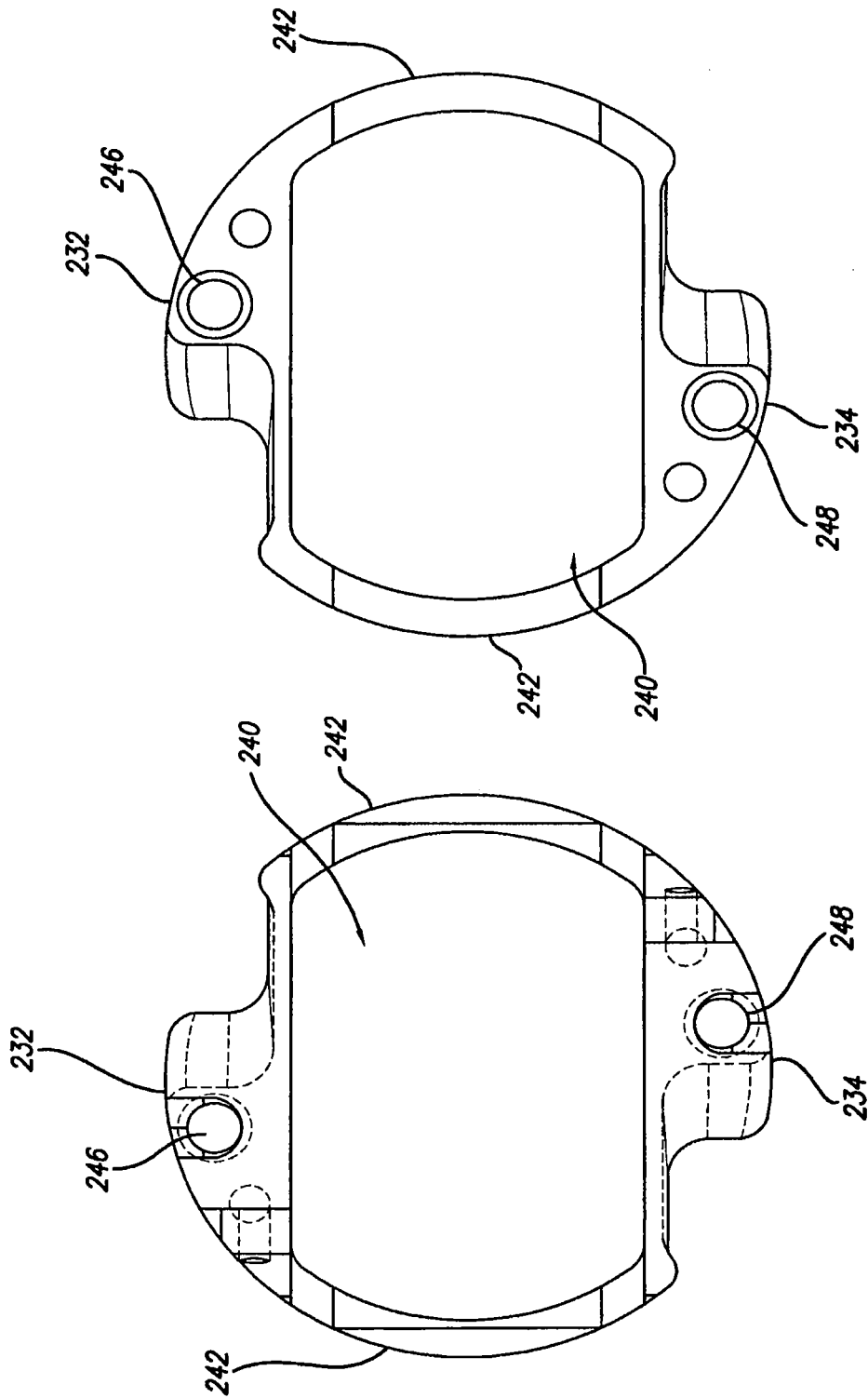


FIG. 12E

FIG. 12D

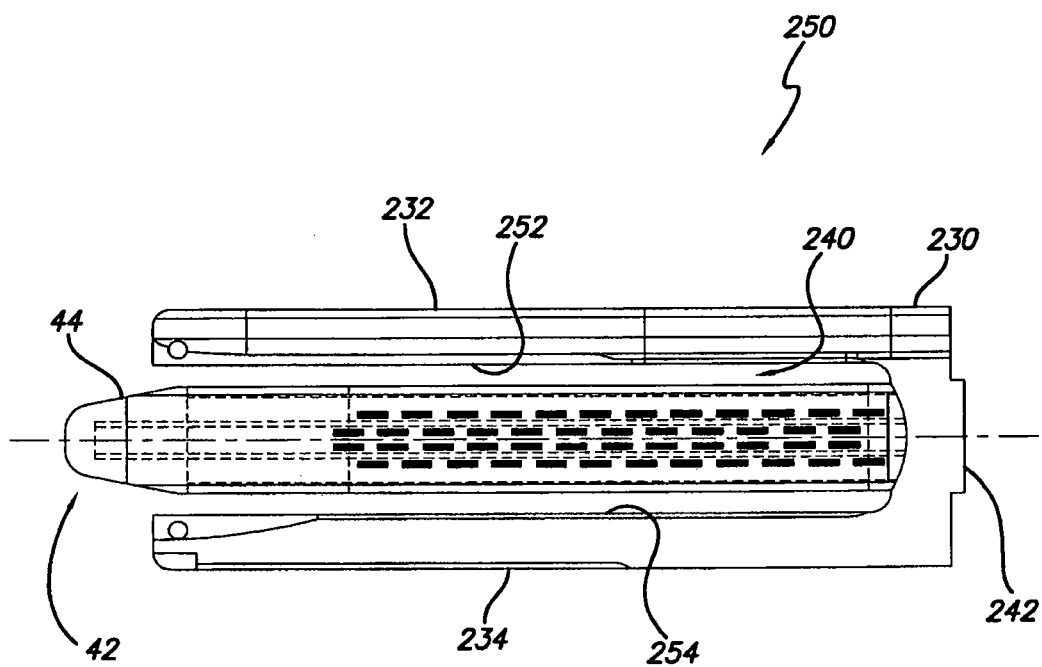


FIG. 13A

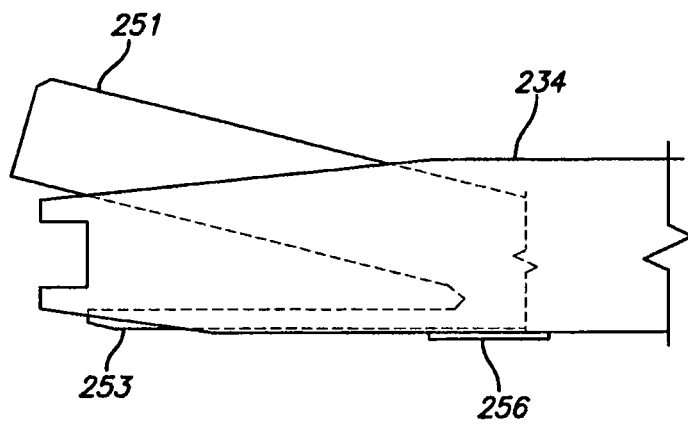


FIG. 13B

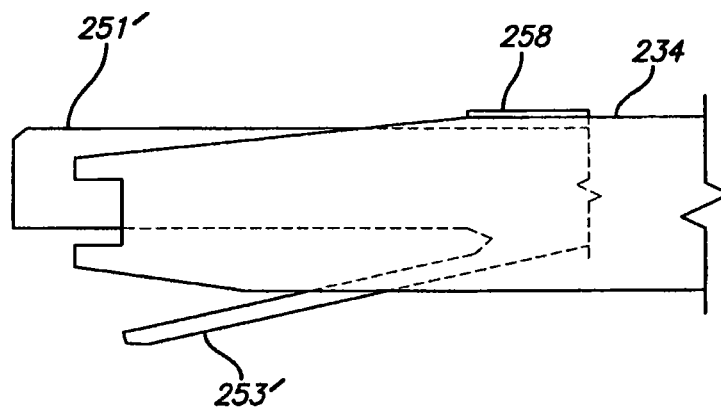


FIG. 13C

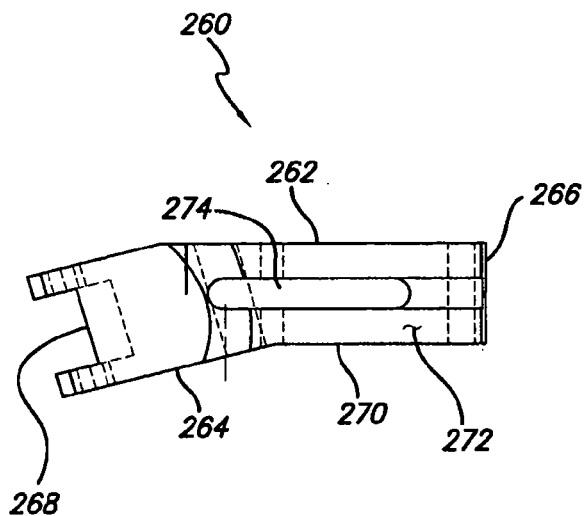


FIG. 14A

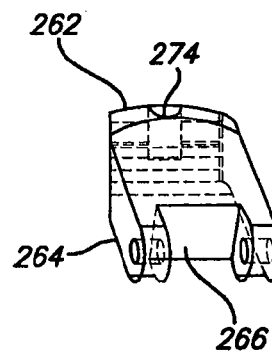


FIG. 14B

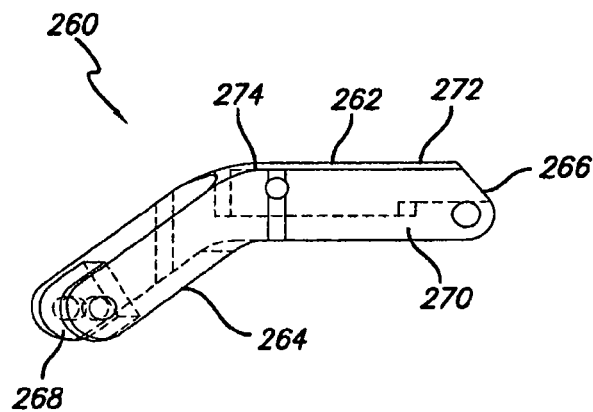


FIG. 14C



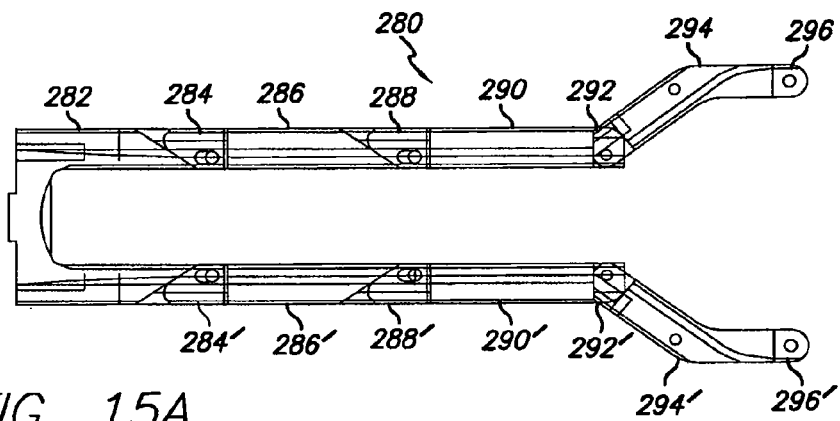


FIG. 15A

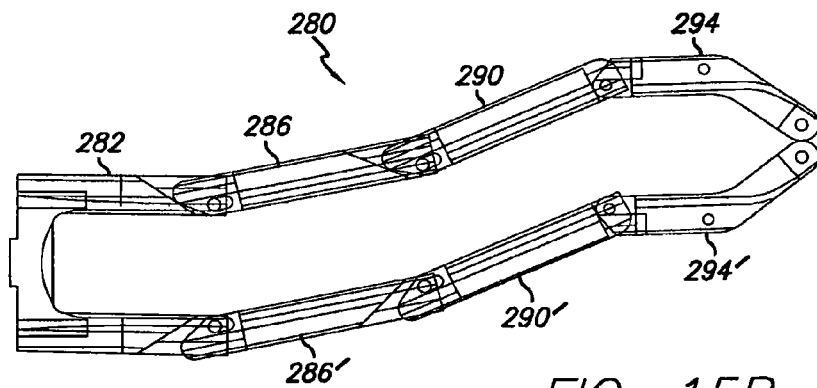


FIG. 15B

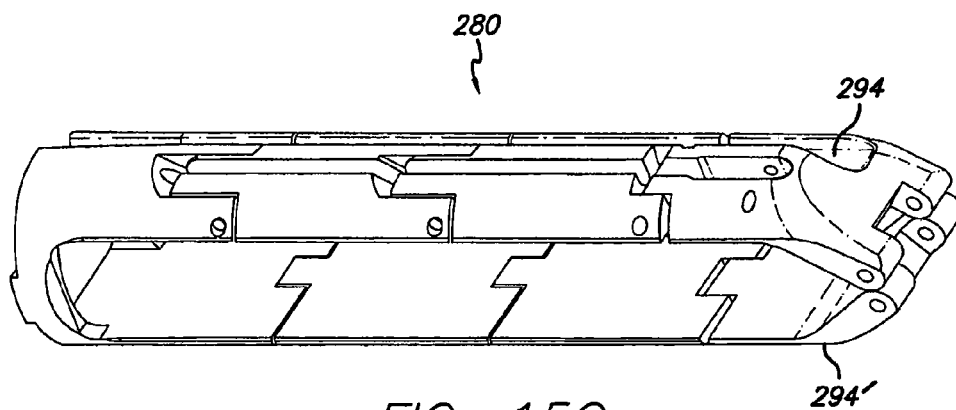


FIG. 15C

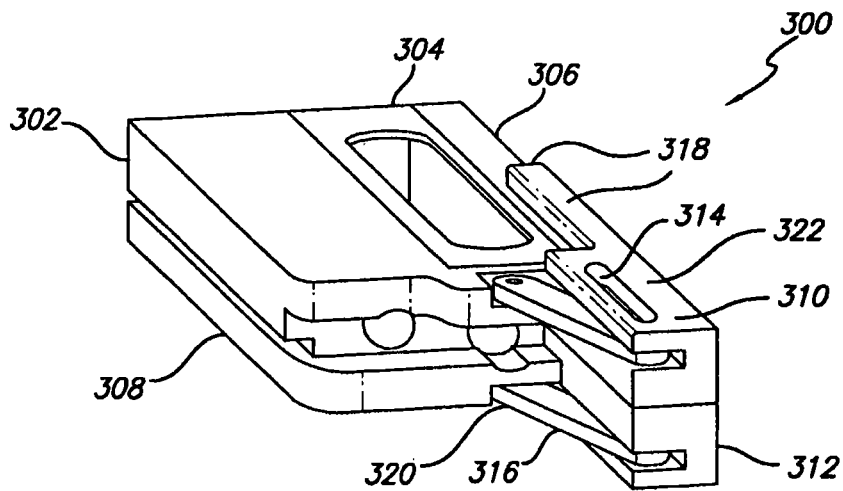


FIG. 16A

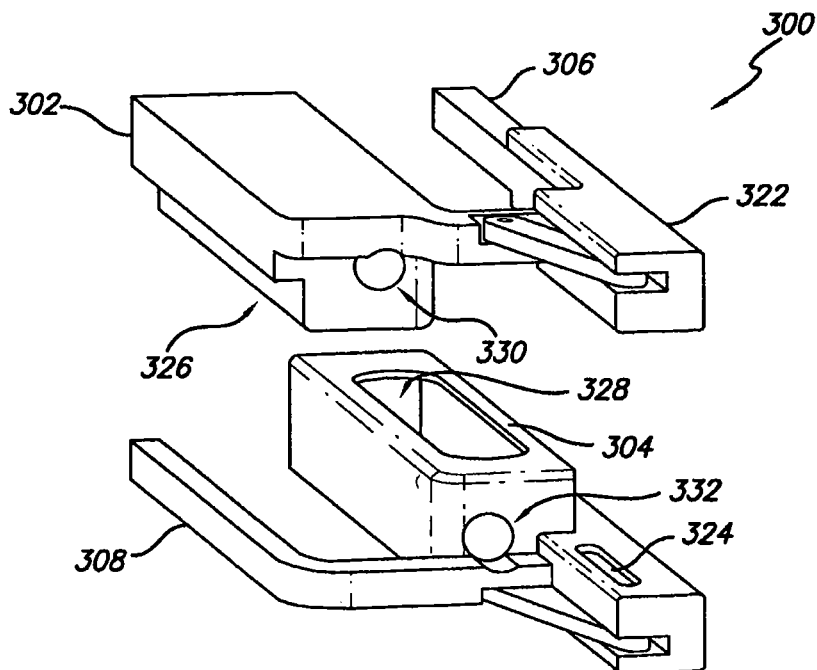


FIG. 16B

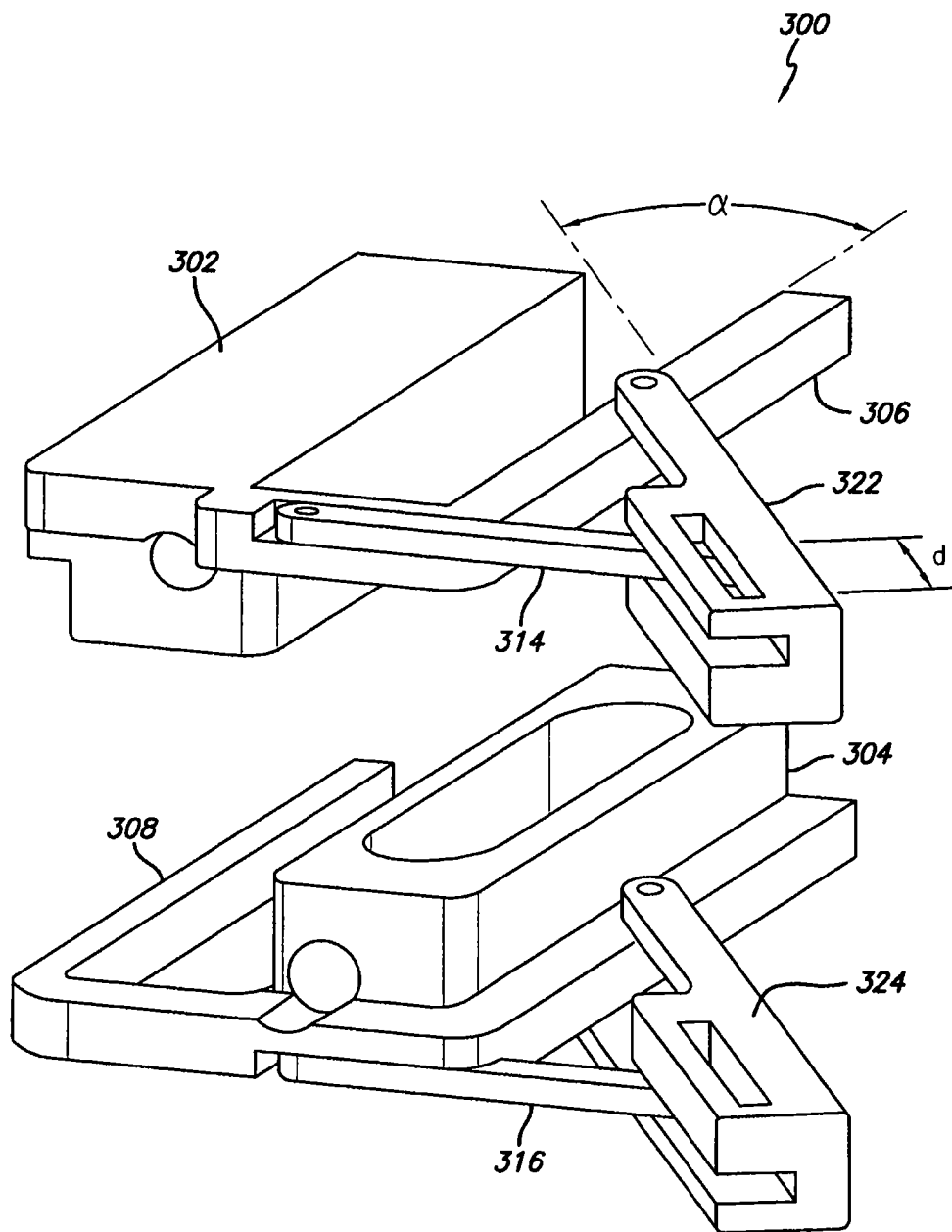
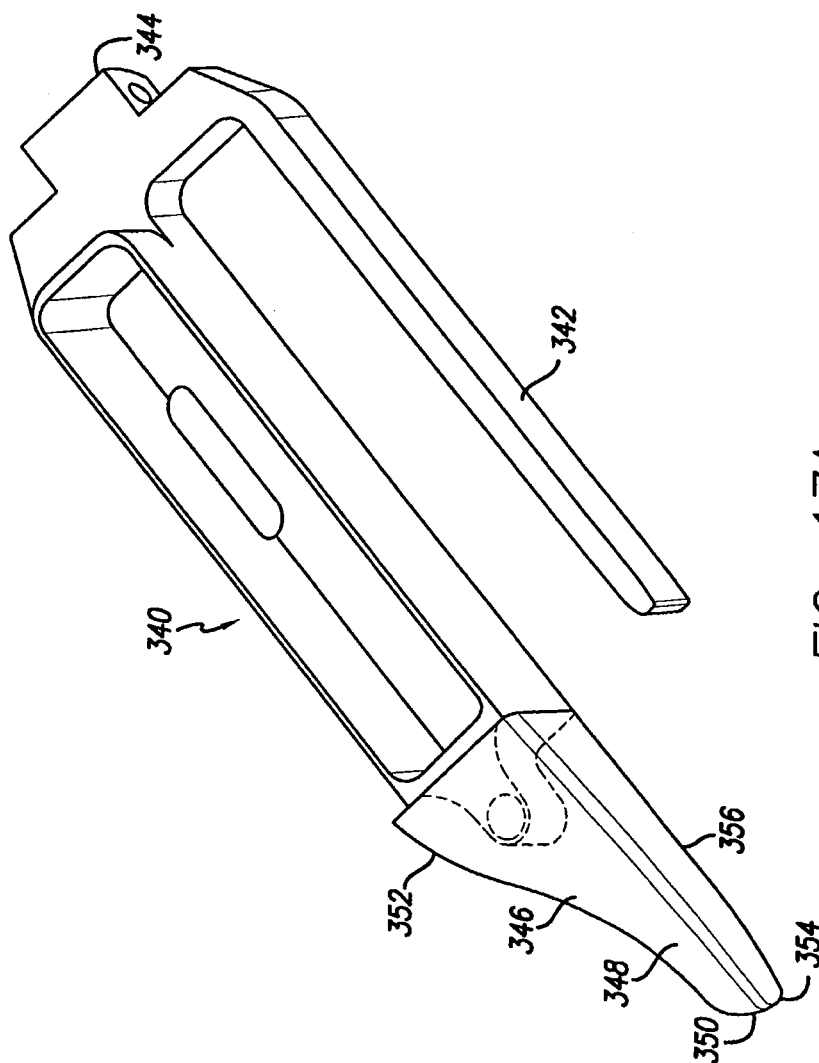


FIG. 16C



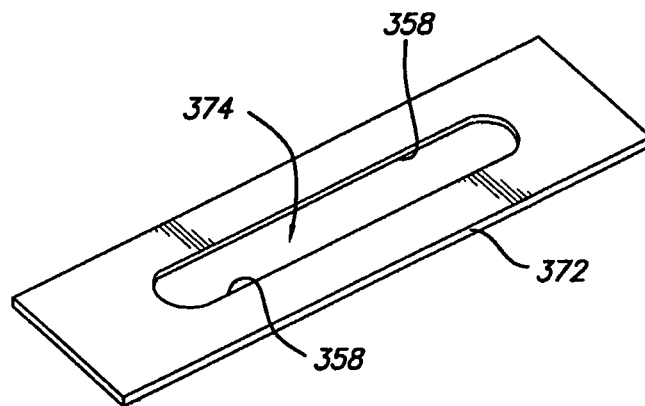


FIG. 17B

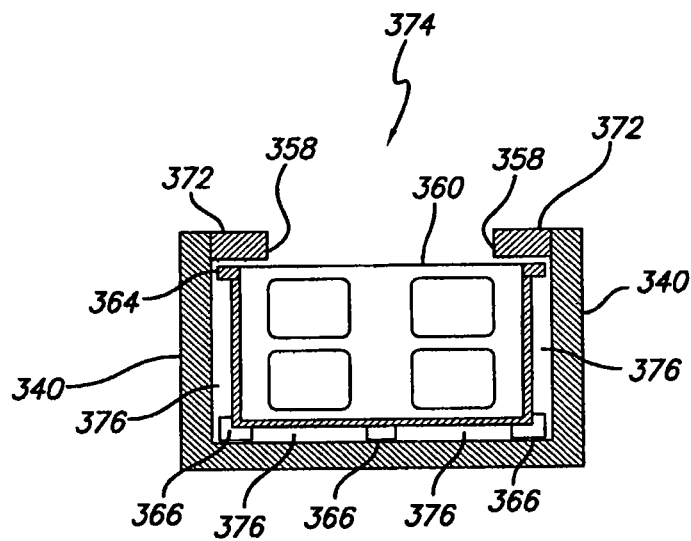


FIG. 17C

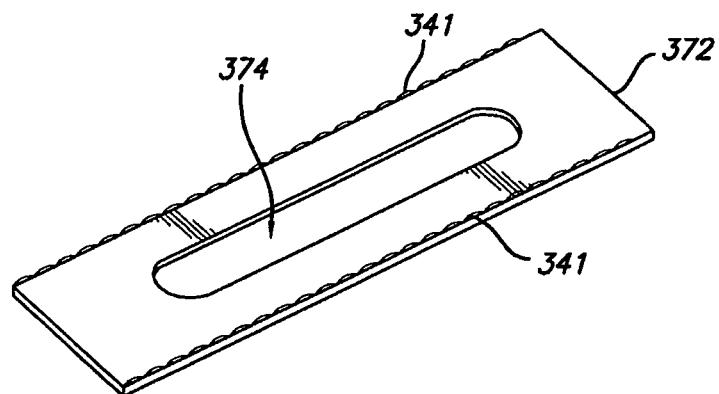


FIG. 17D

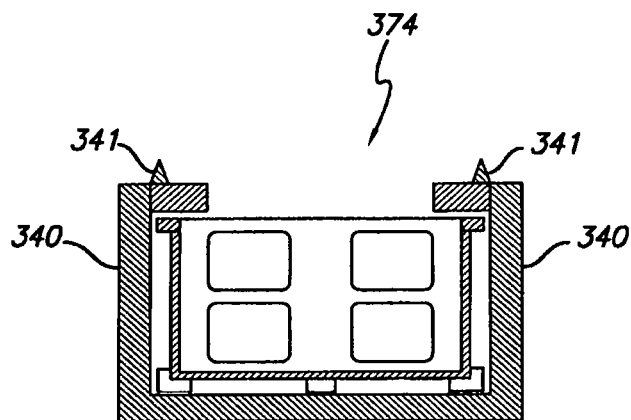


FIG. 17E

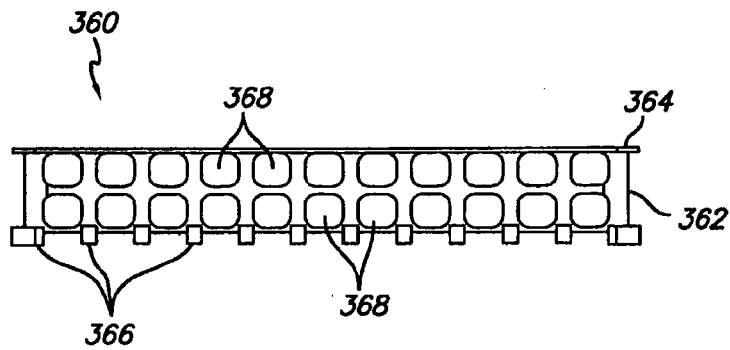


FIG. 18A

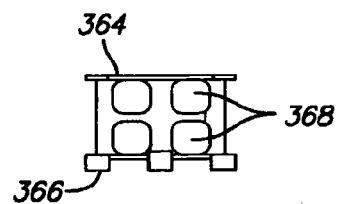


FIG. 18B

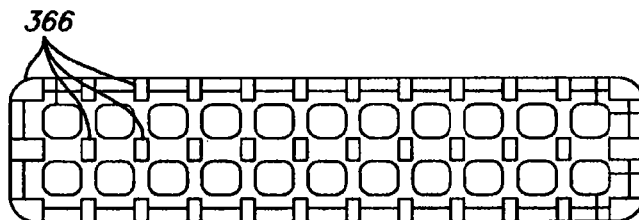


FIG. 18C

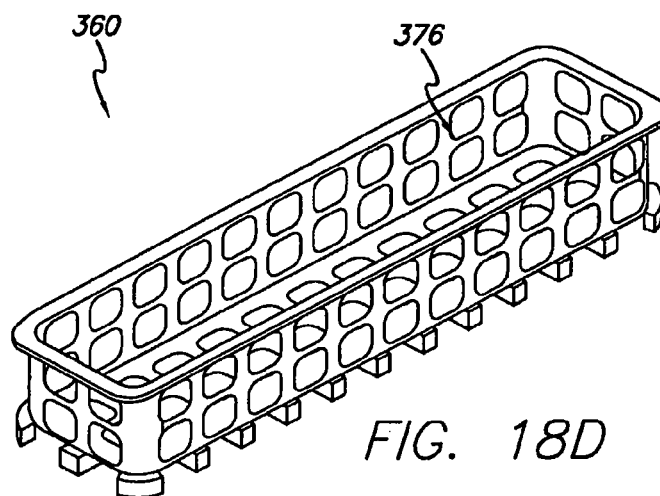


FIG. 18D

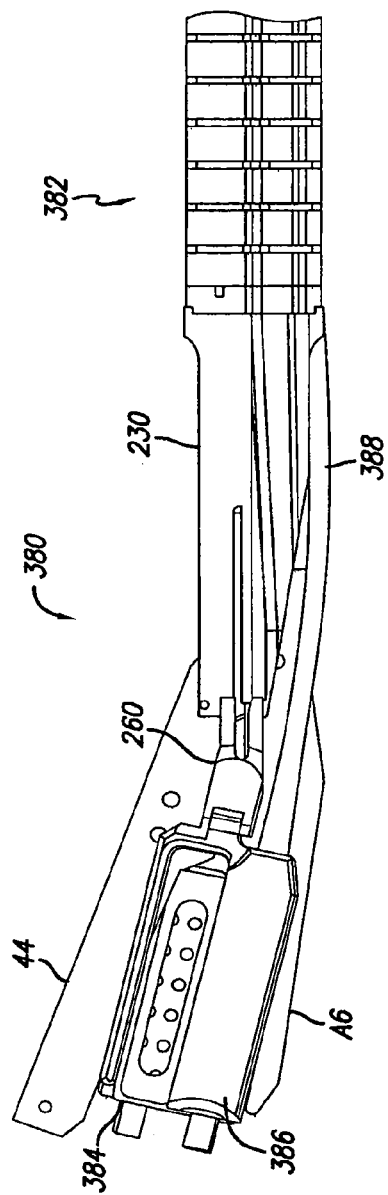


FIG. 19A

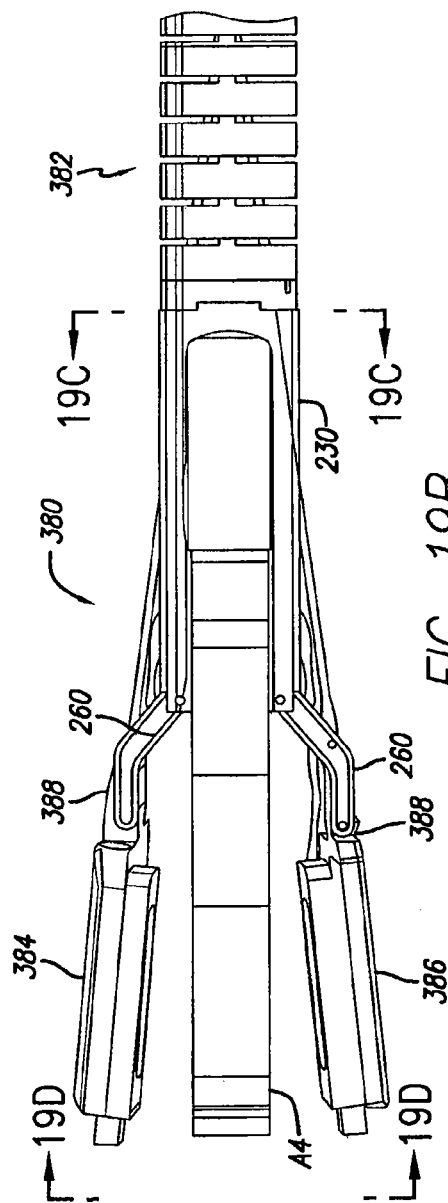
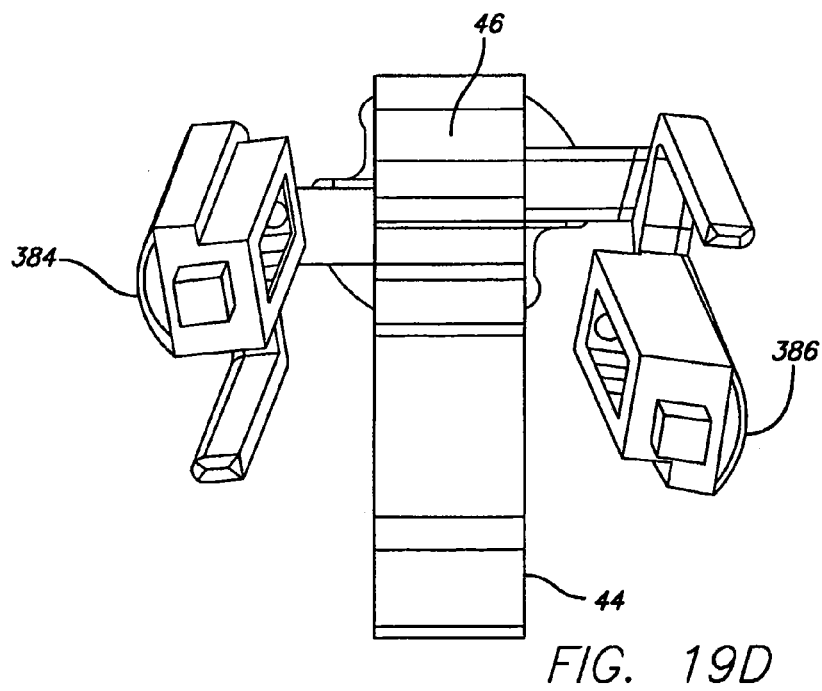
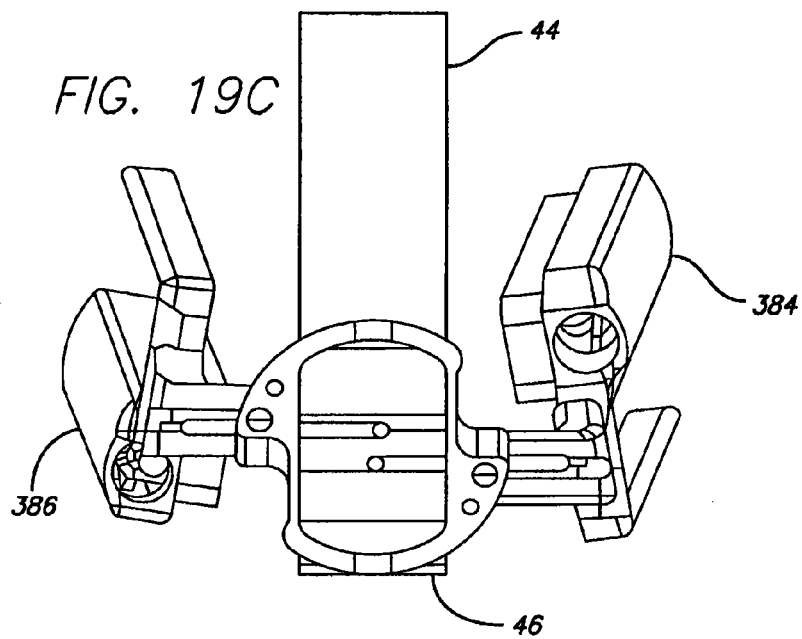


FIG. 19B





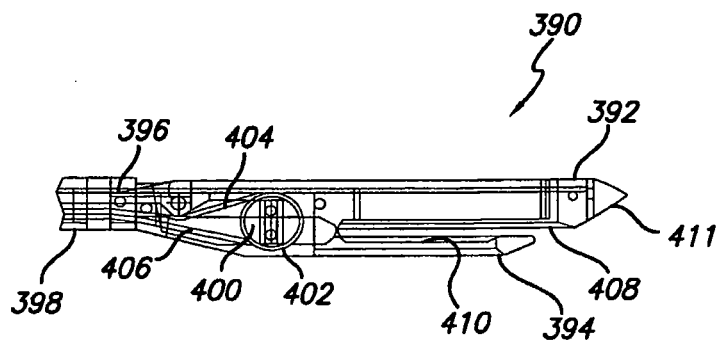


FIG. 20A

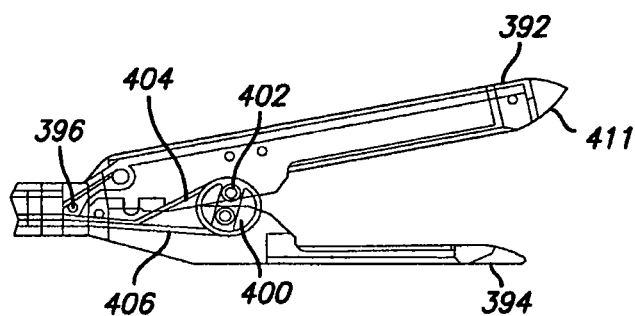


FIG. 20B

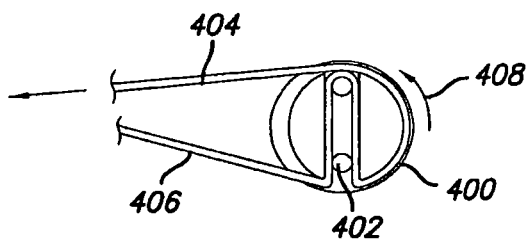


FIG. 21A

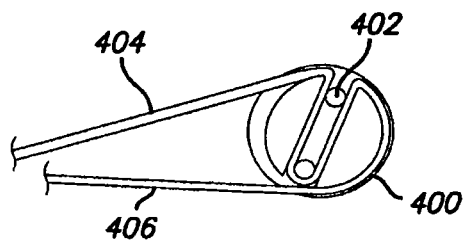
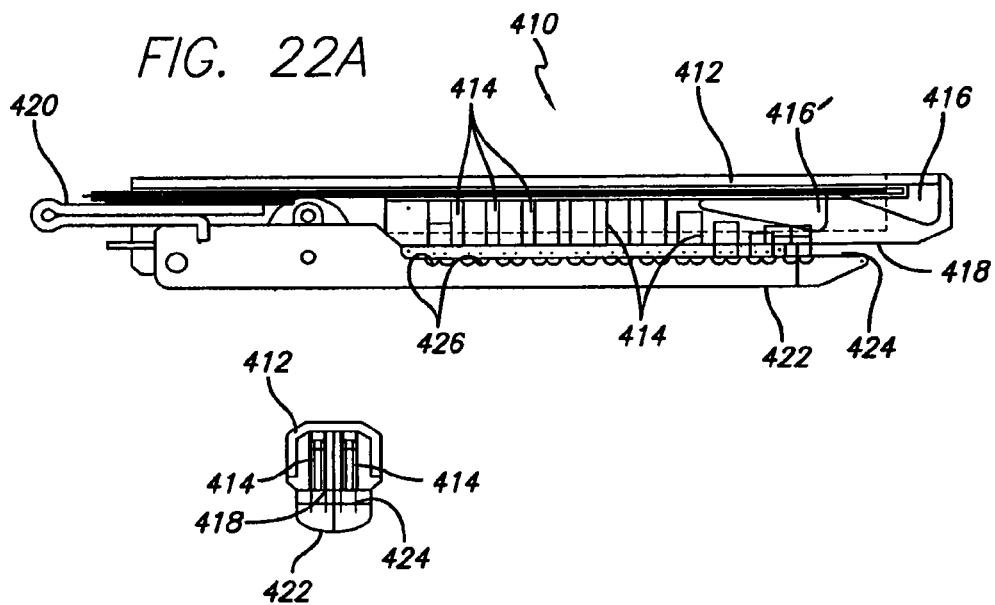
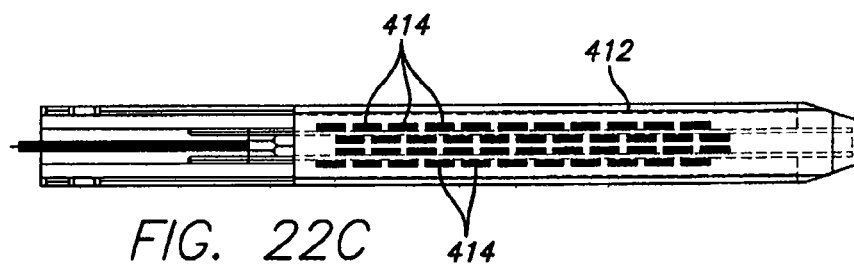


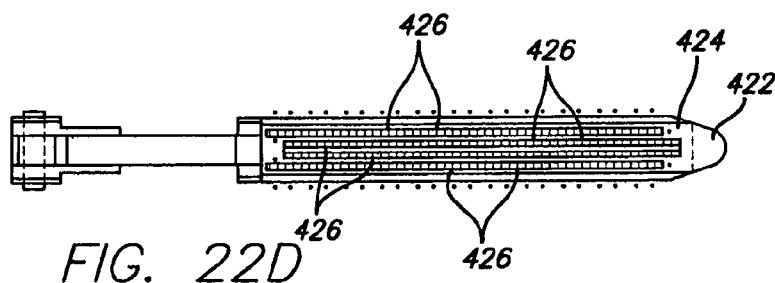
FIG. 21B



*FIG. 22B*



*FIG. 22C*



*FIG. 22D*

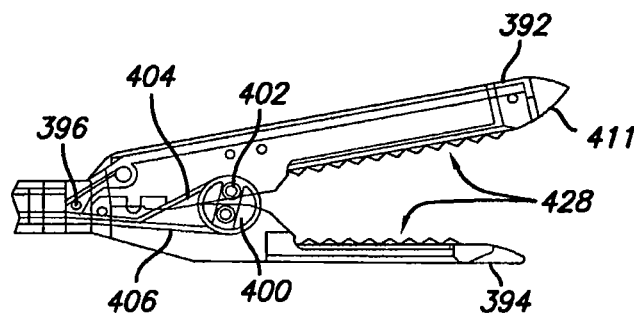


FIG. 22E

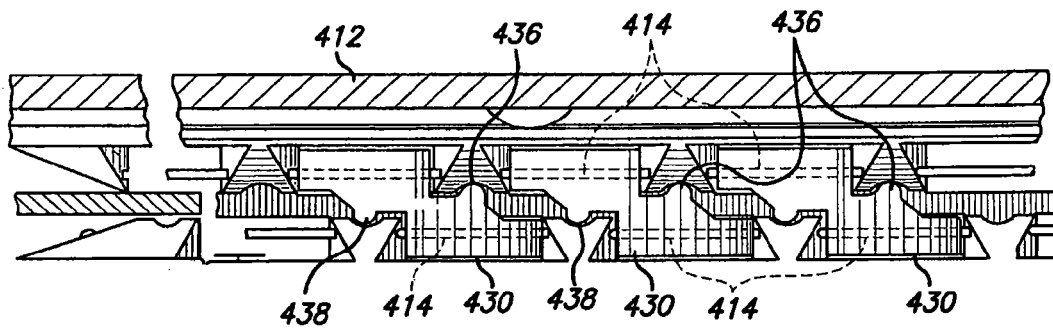


FIG. 23A

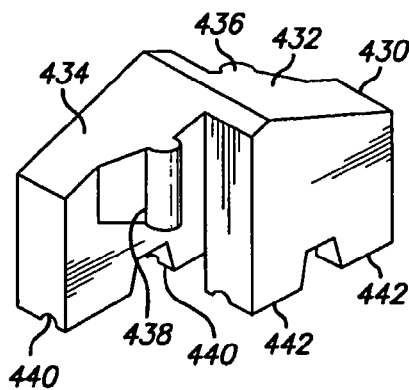


FIG. 23B

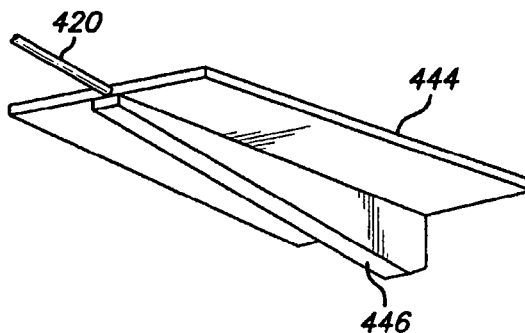


FIG. 23C

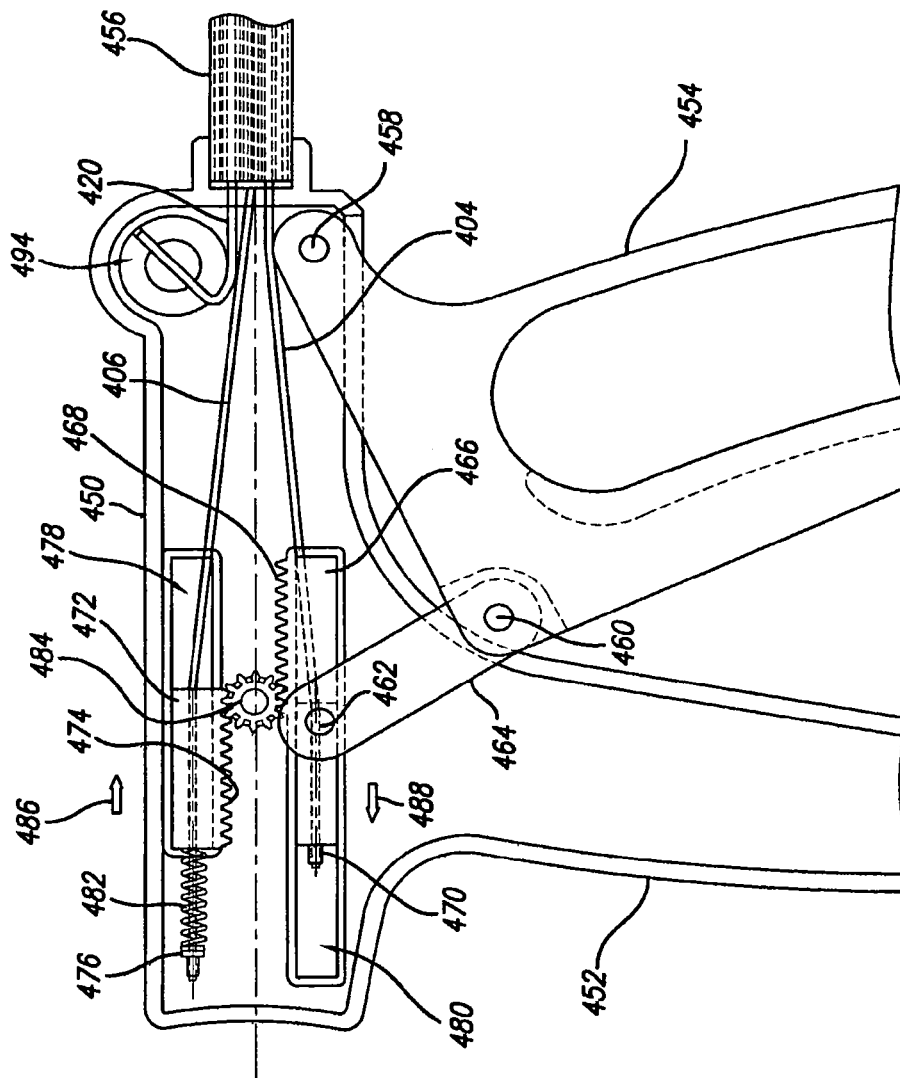


FIG. 24A

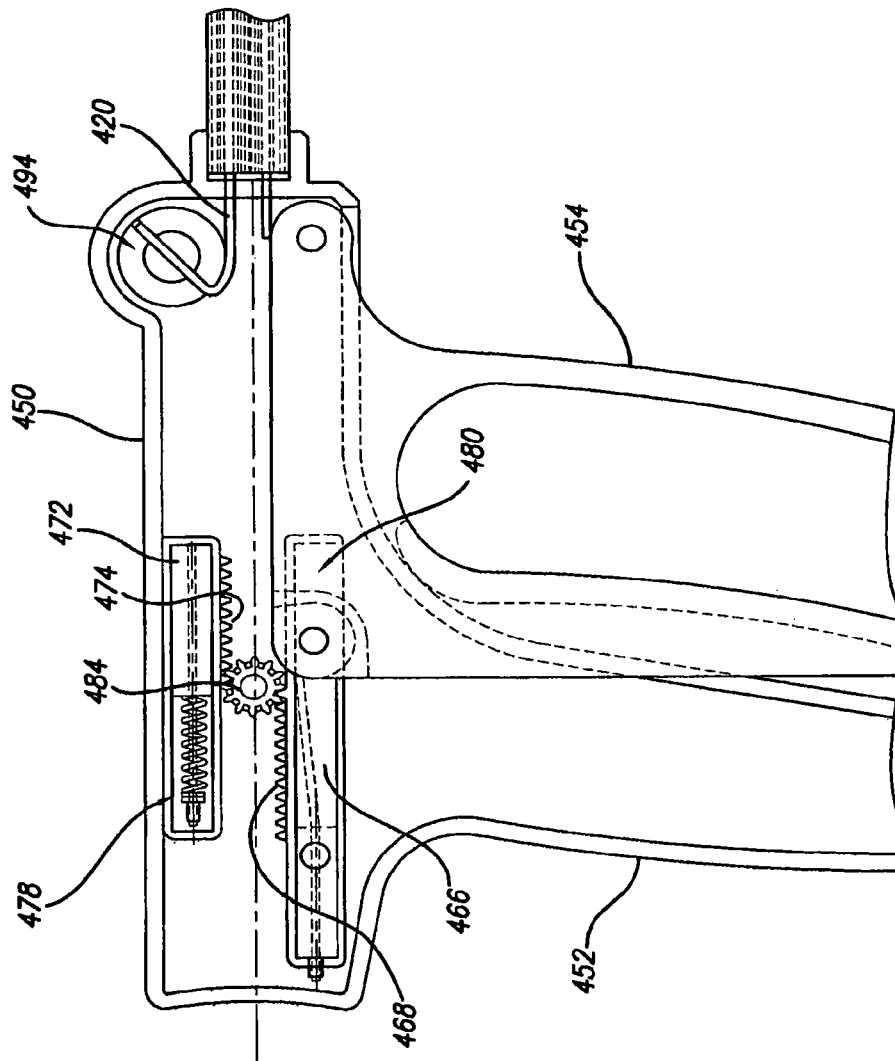
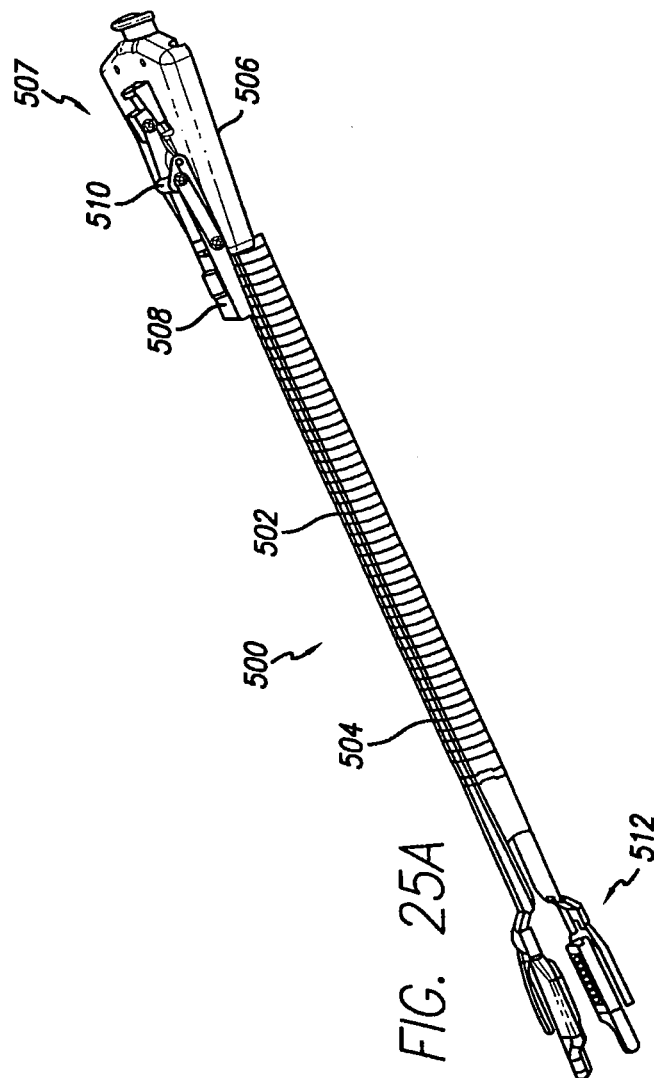


FIG. 24B





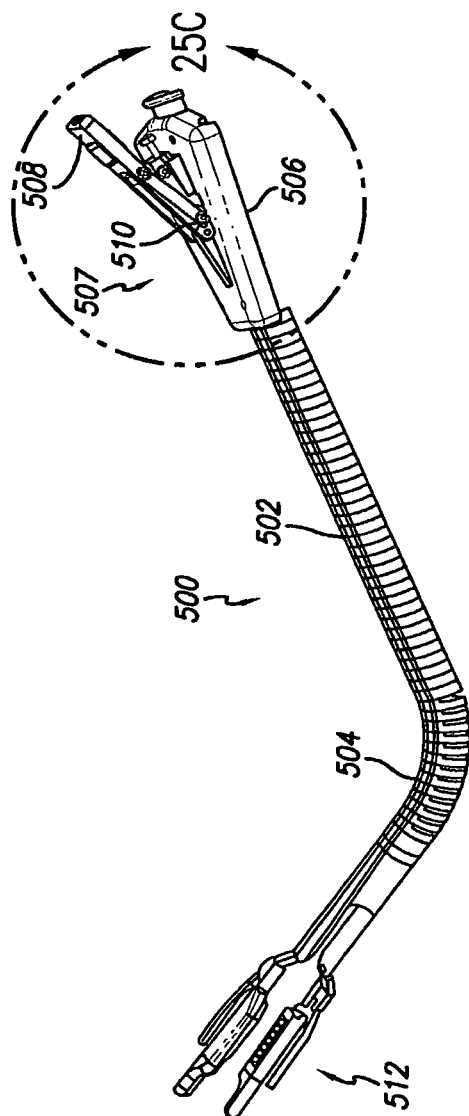


FIG. 25B

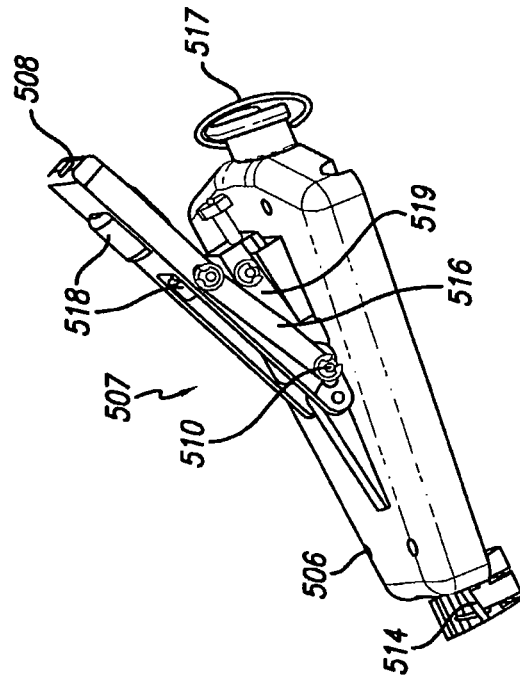


FIG. 25C

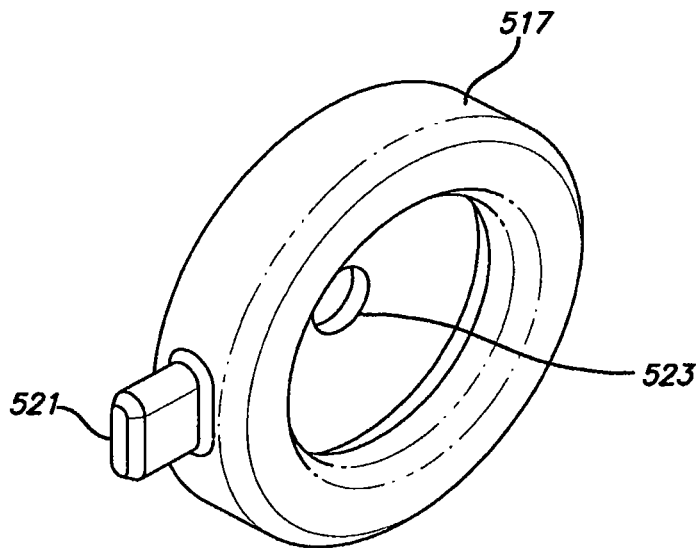


FIG. 25D

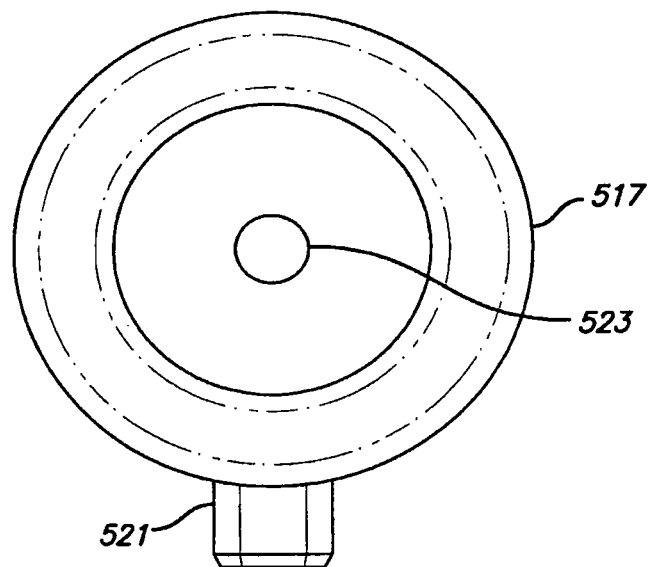
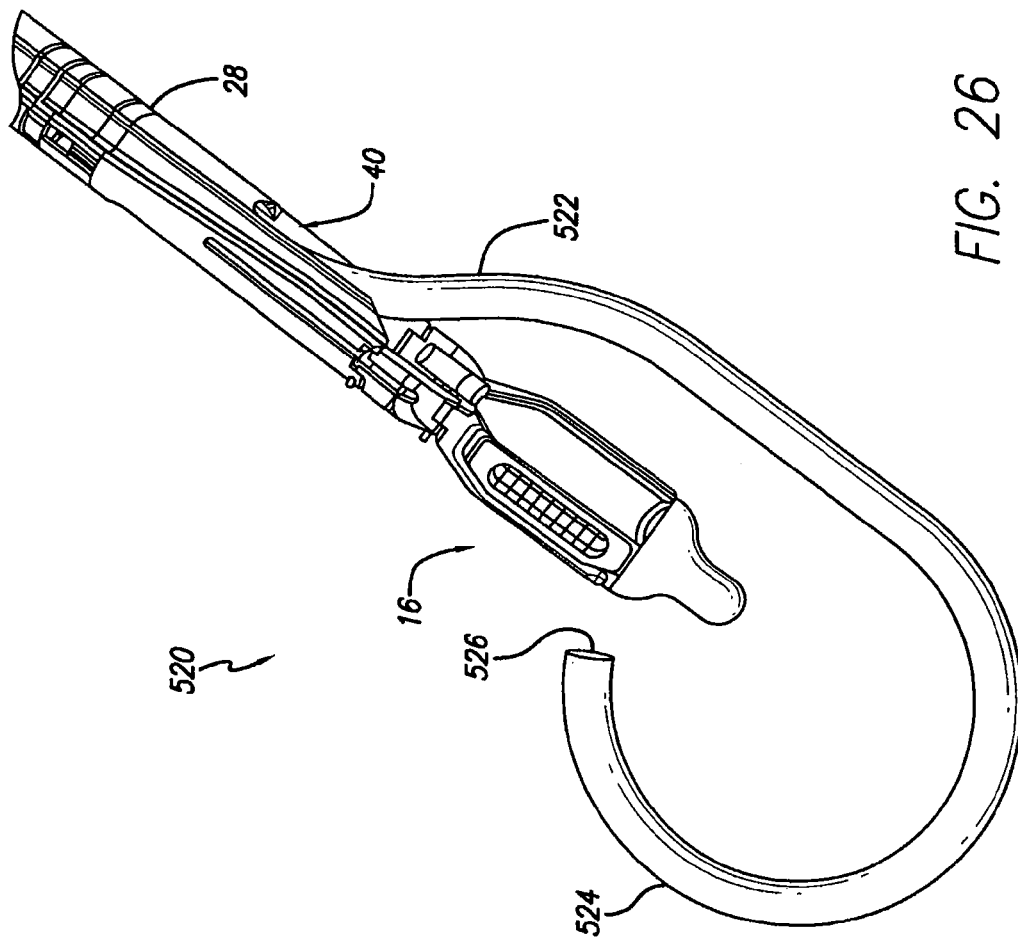


FIG. 25E



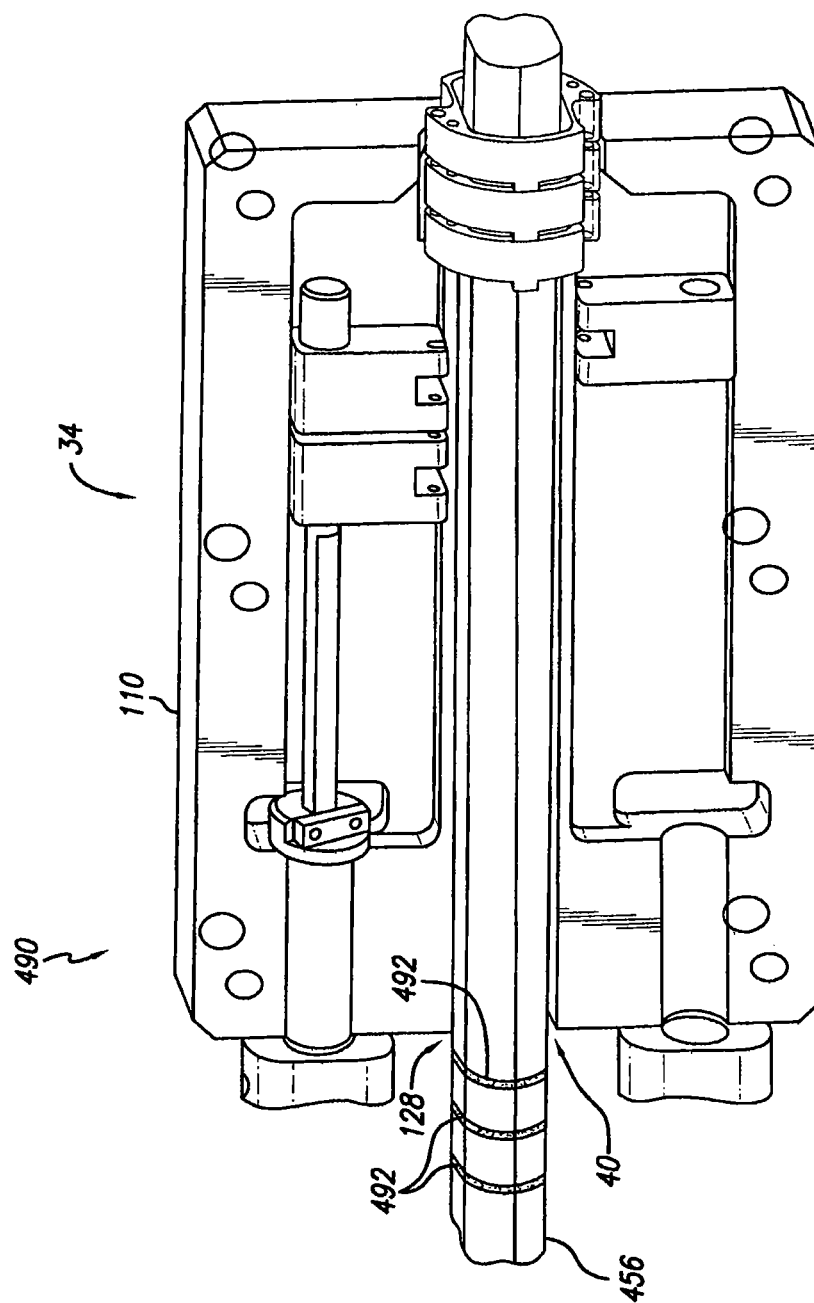


FIG. 27

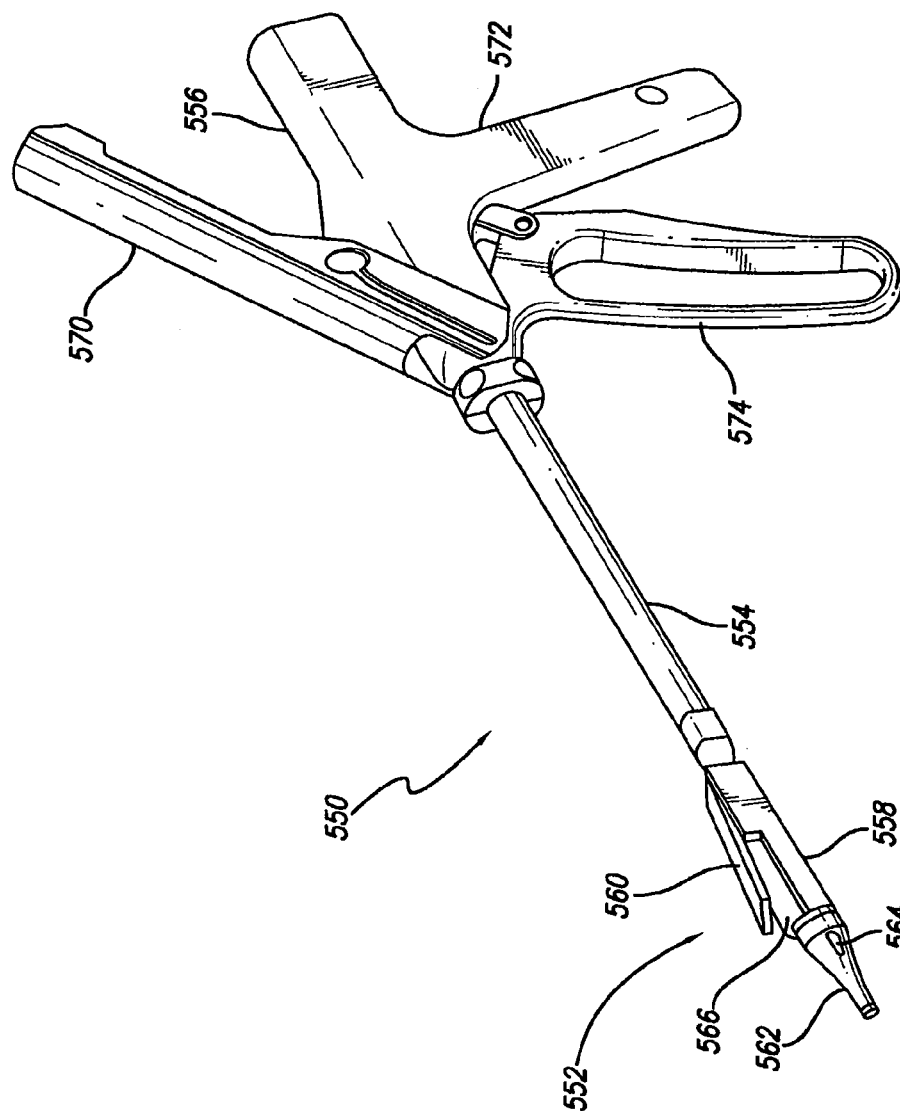


FIG. 28

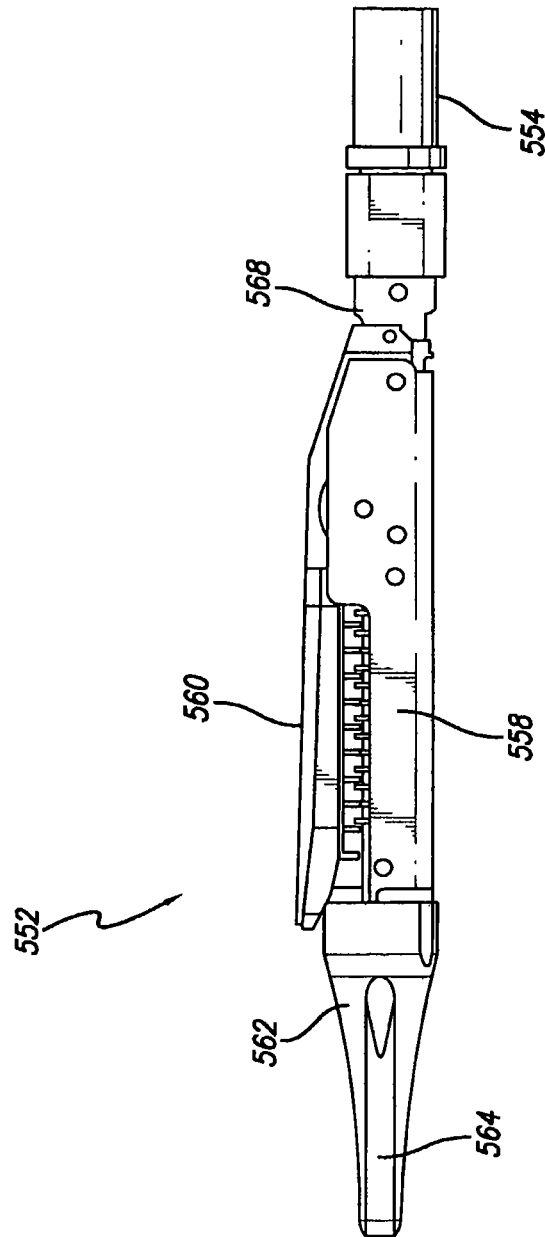
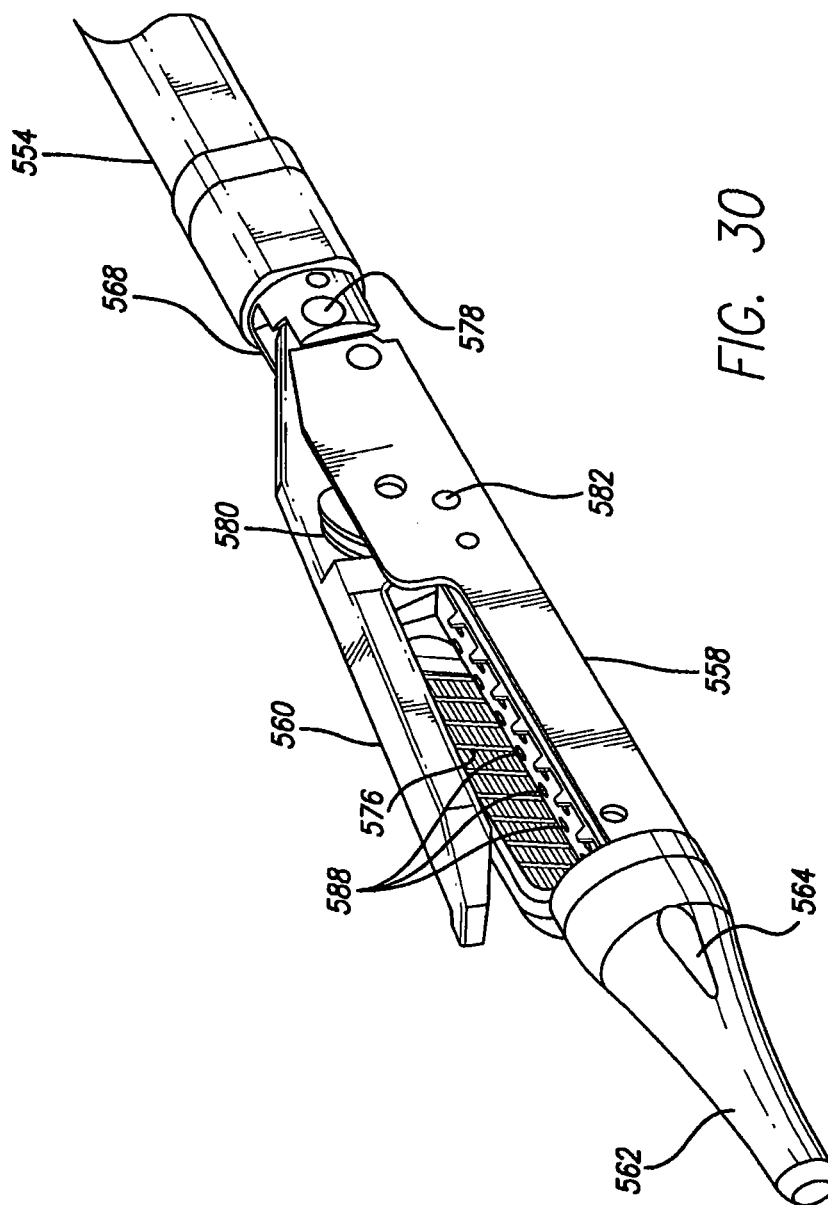


FIG. 29





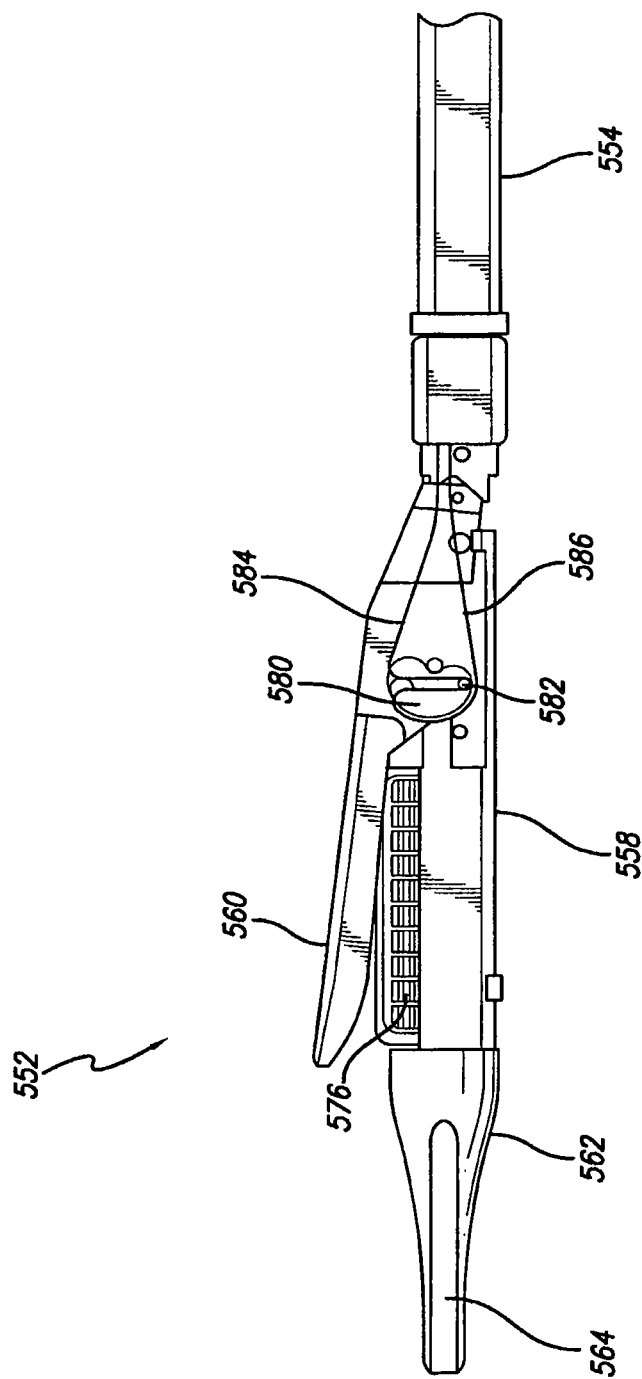


FIG. 31

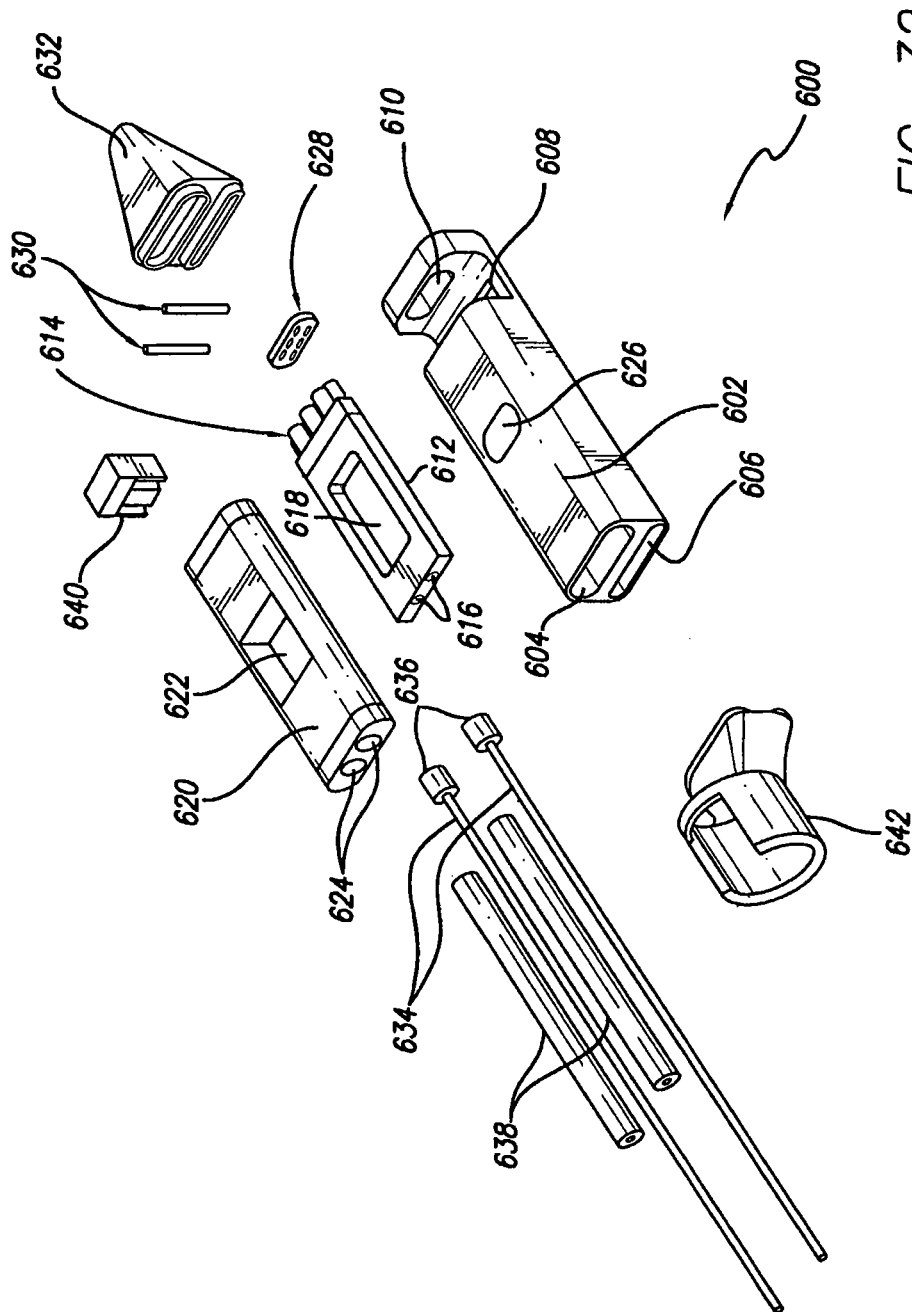


FIG. 32

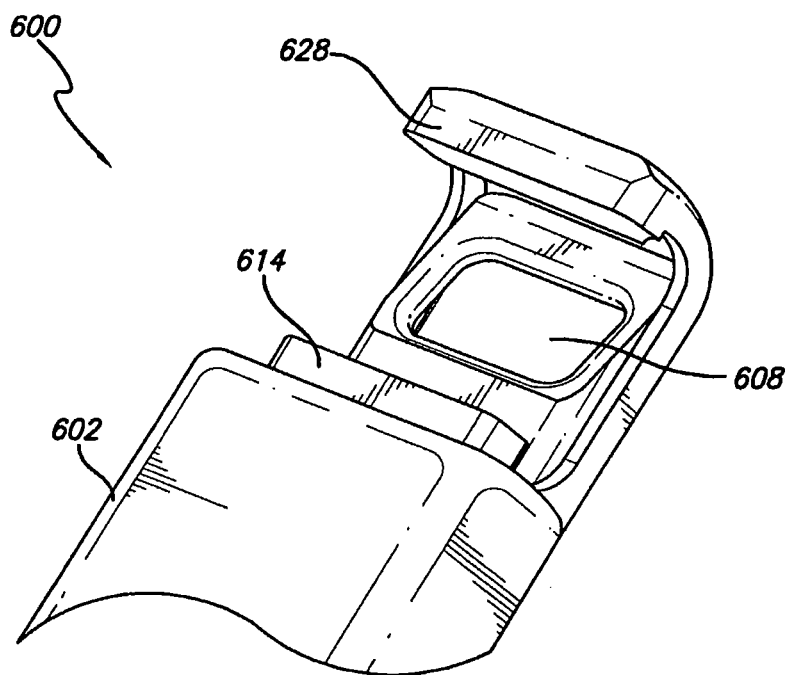
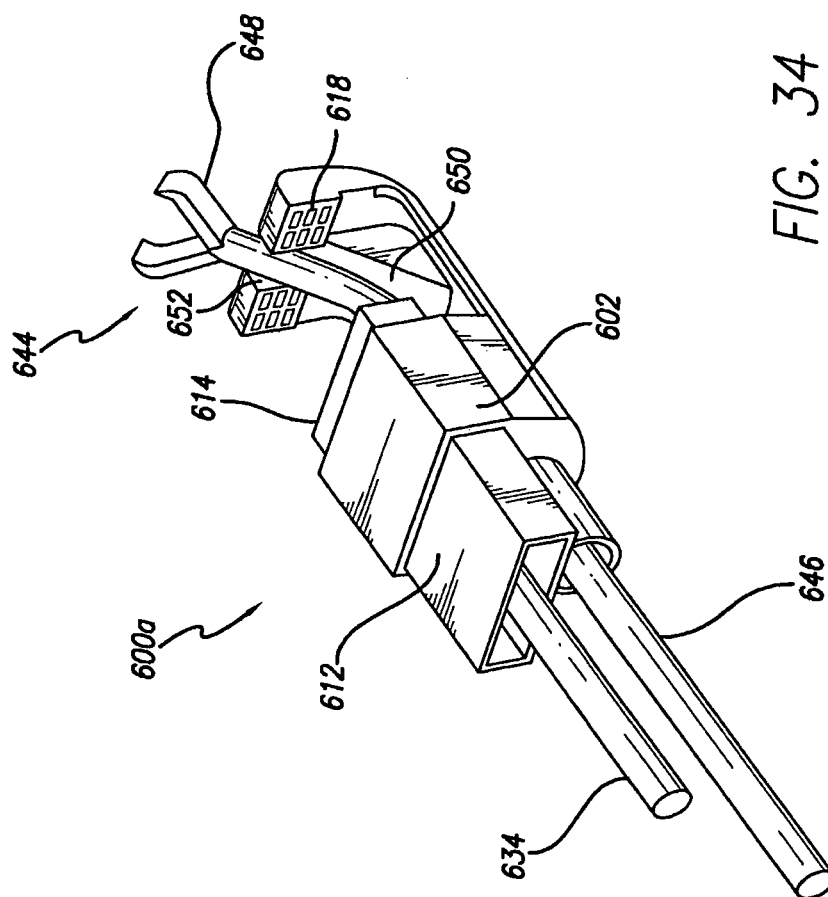


FIG. 33



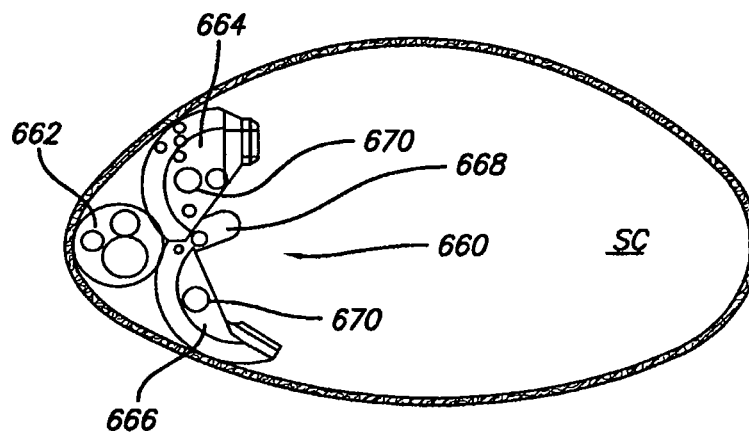


FIG. 35

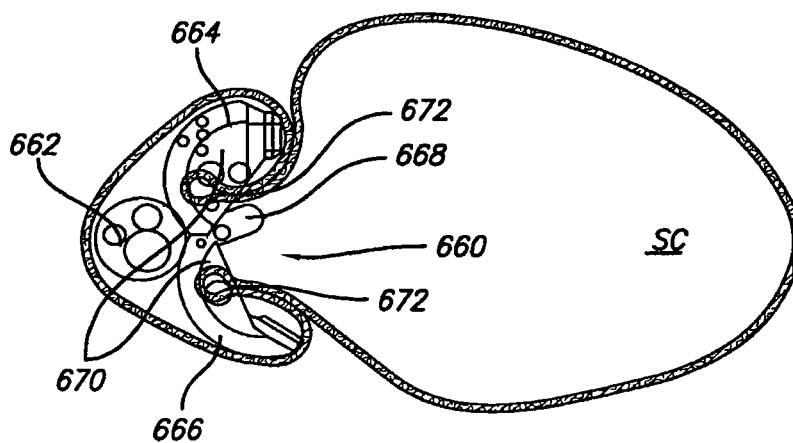


FIG. 36

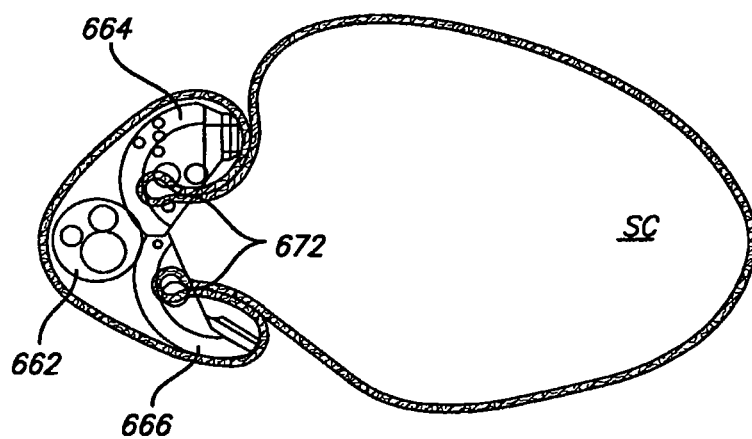


FIG. 37

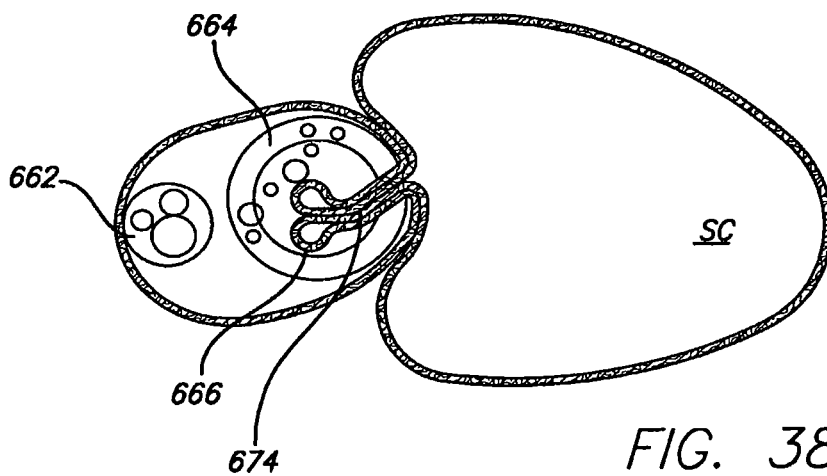


FIG. 38

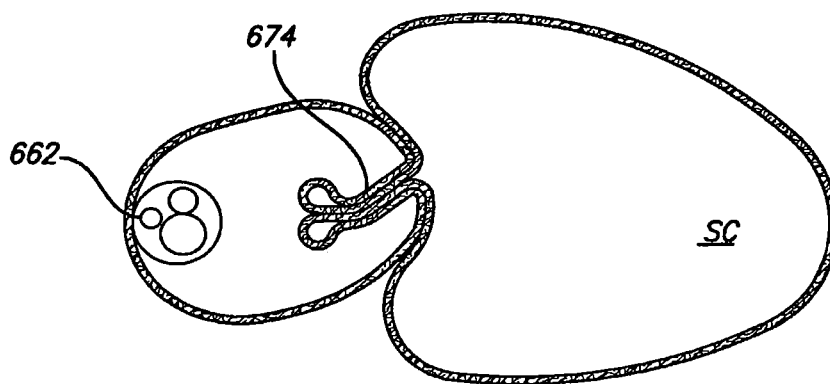


FIG. 39

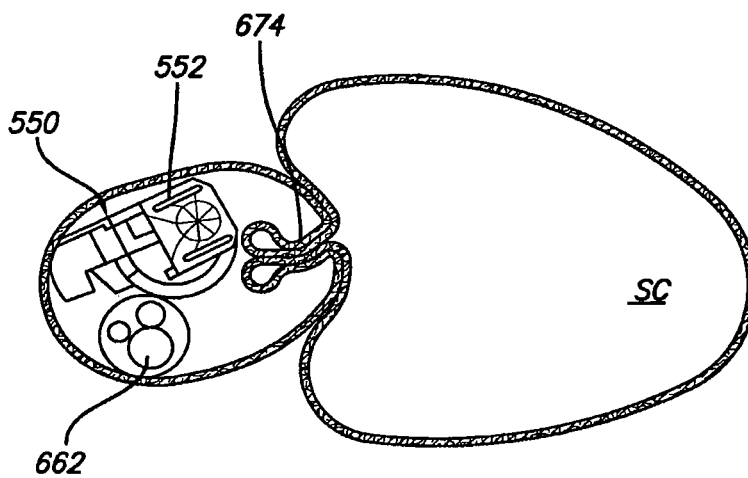


FIG. 40

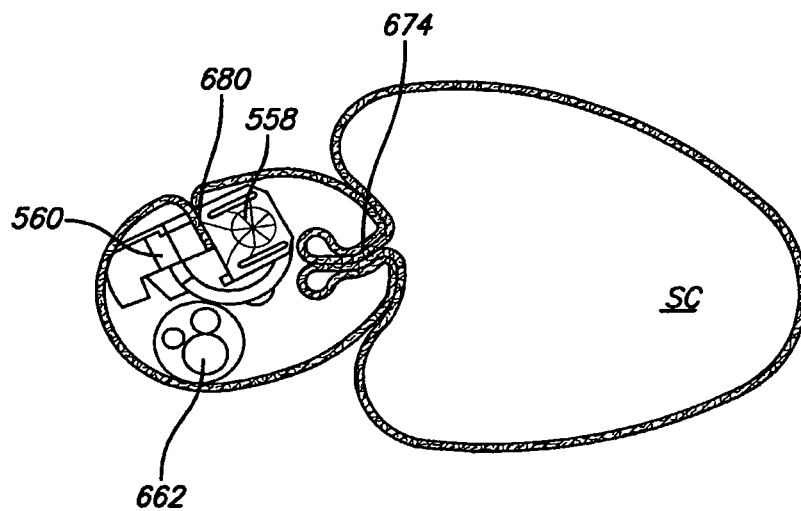


FIG. 41

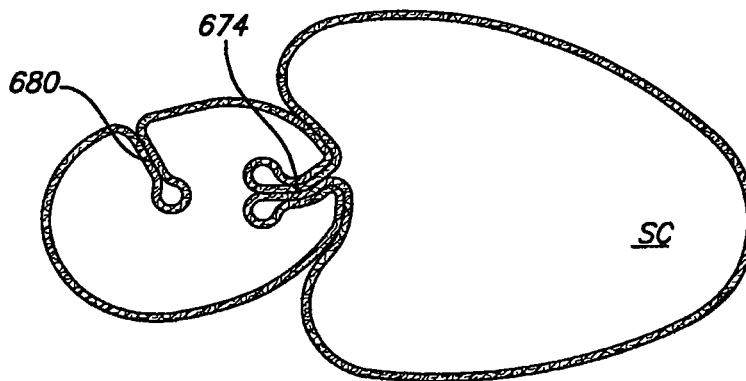
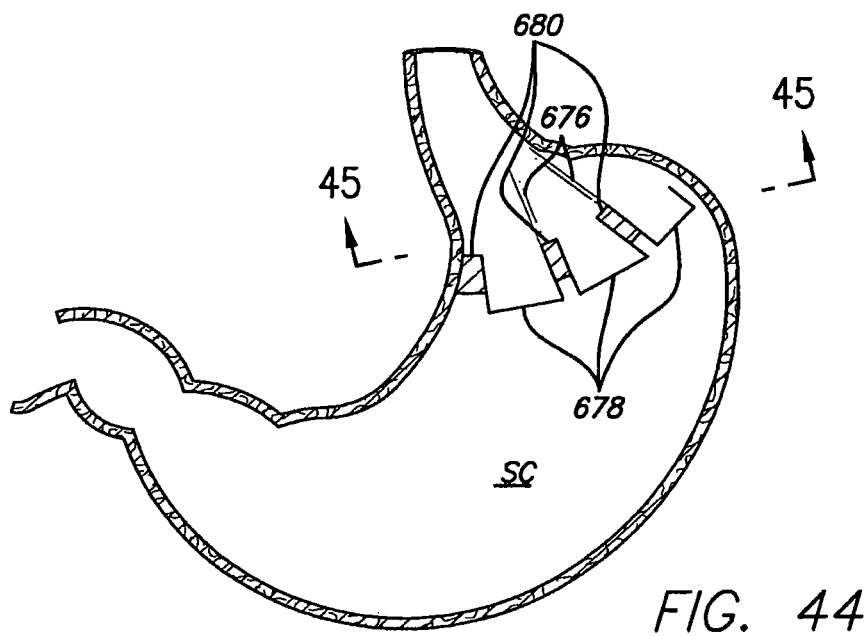
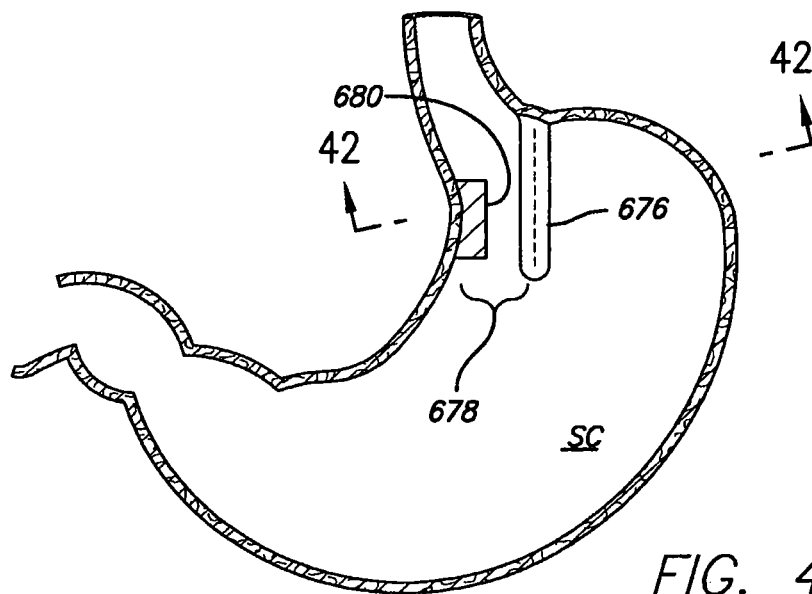


FIG. 42





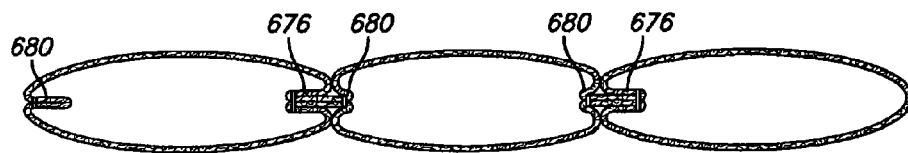


FIG. 45

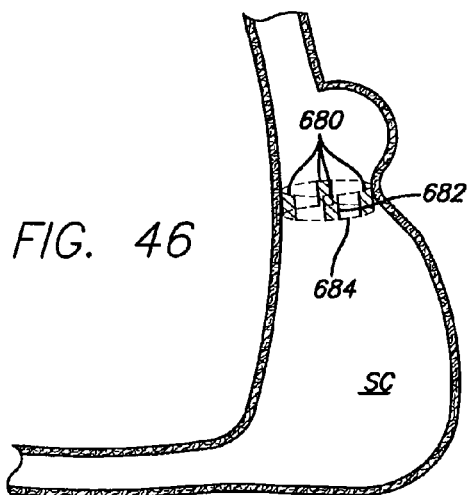


FIG. 46

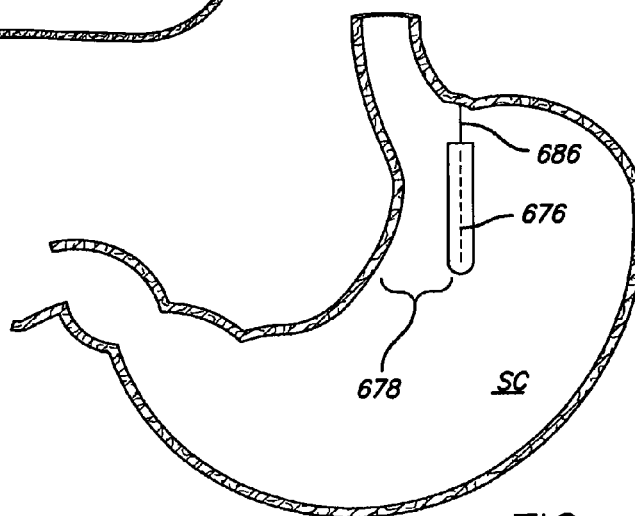


FIG. 47

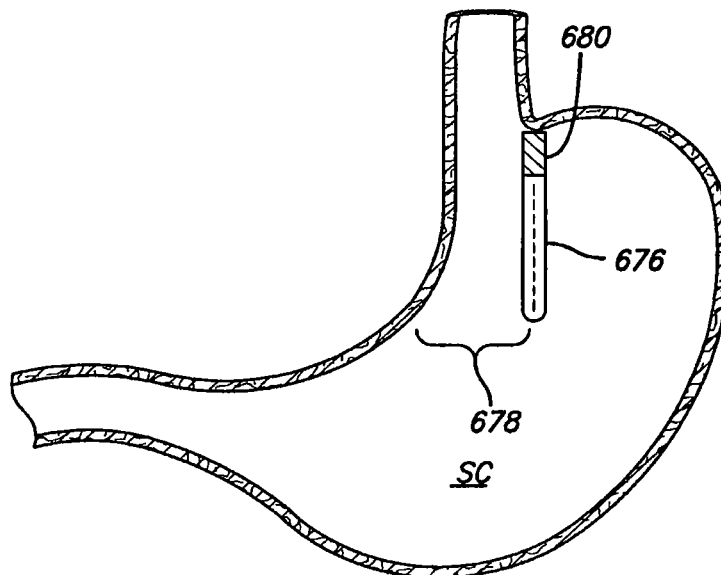


FIG. 48

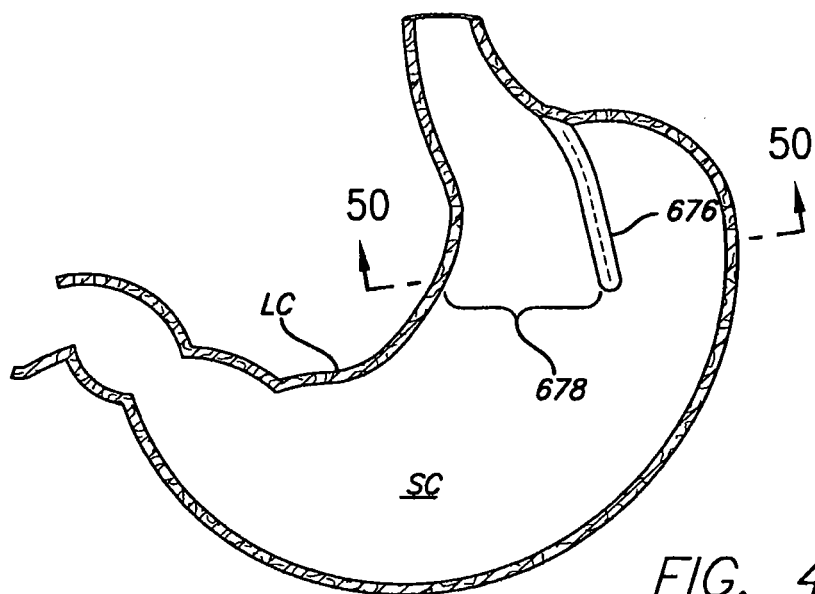


FIG. 49

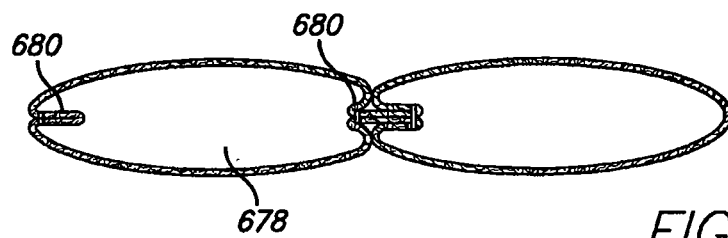


FIG. 50A

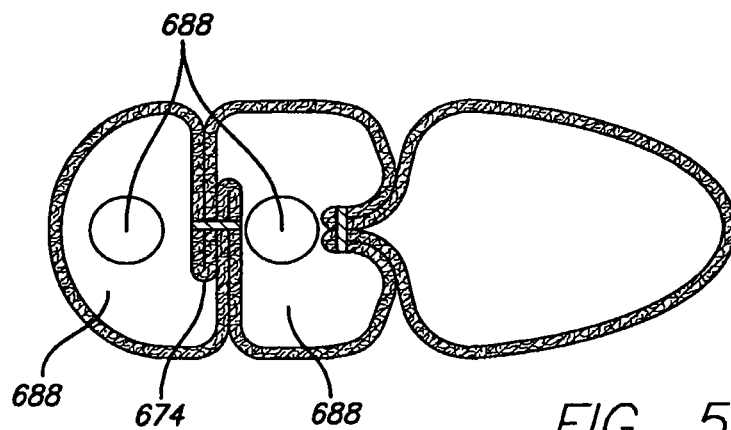


FIG. 50B

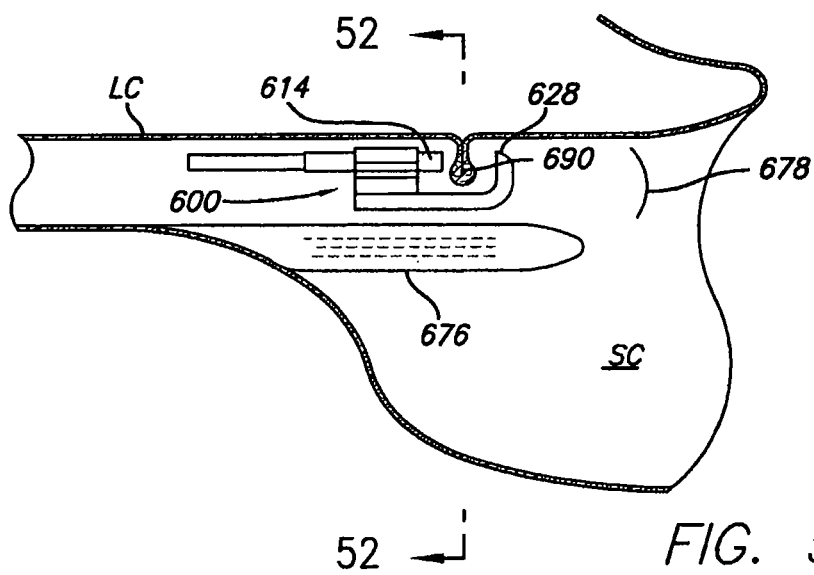


FIG. 51

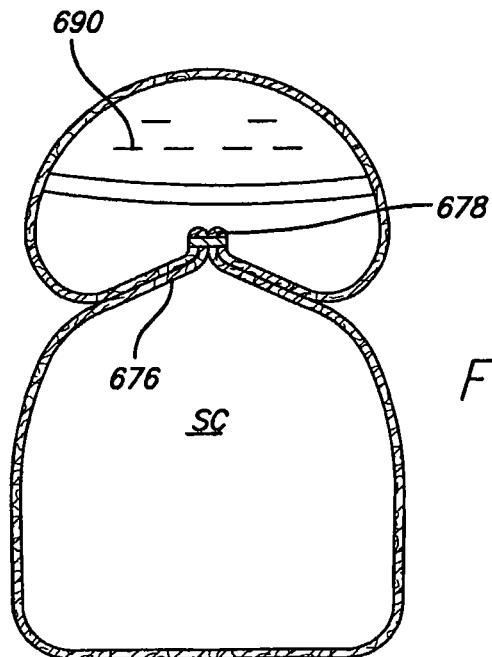


FIG. 52

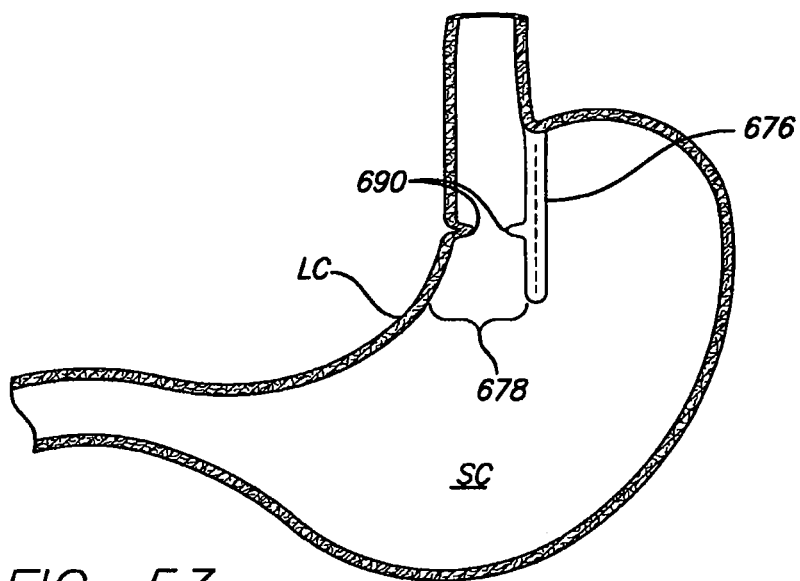


FIG. 53

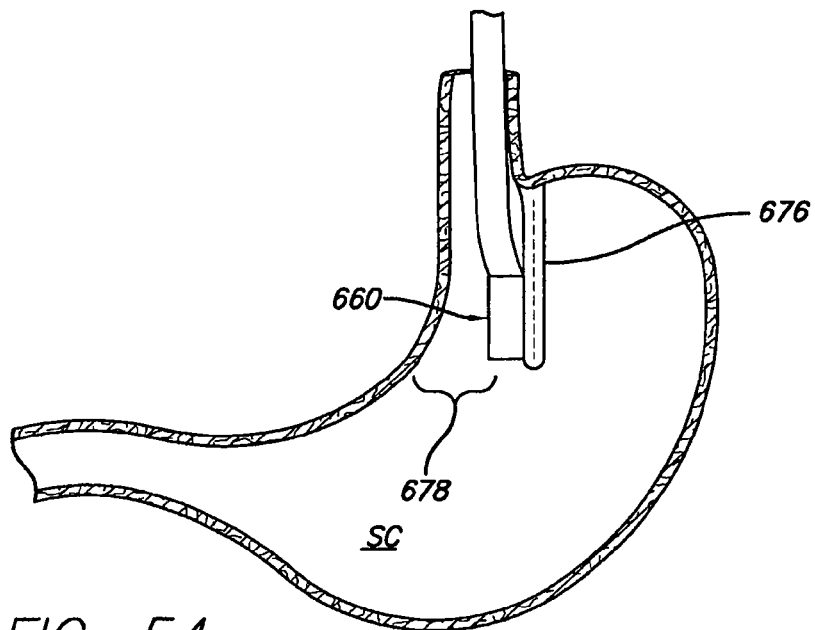


FIG. 54

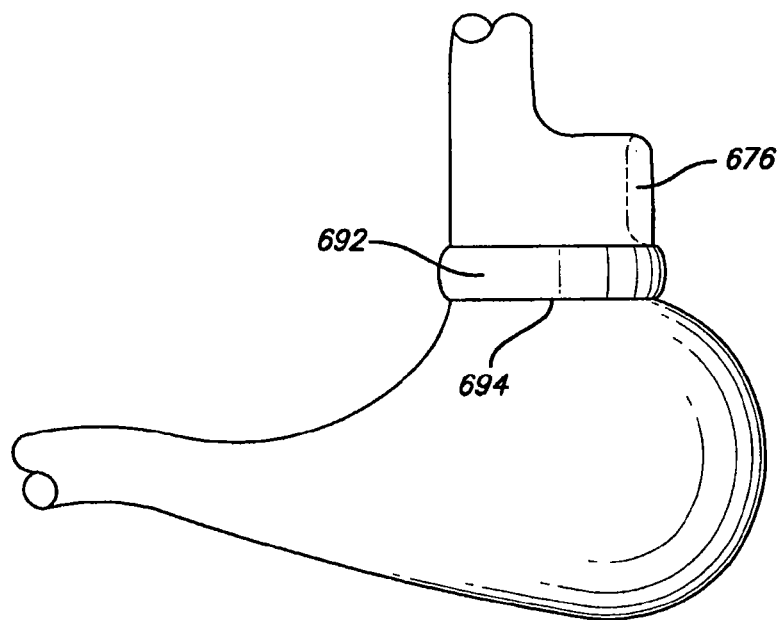


FIG. 55

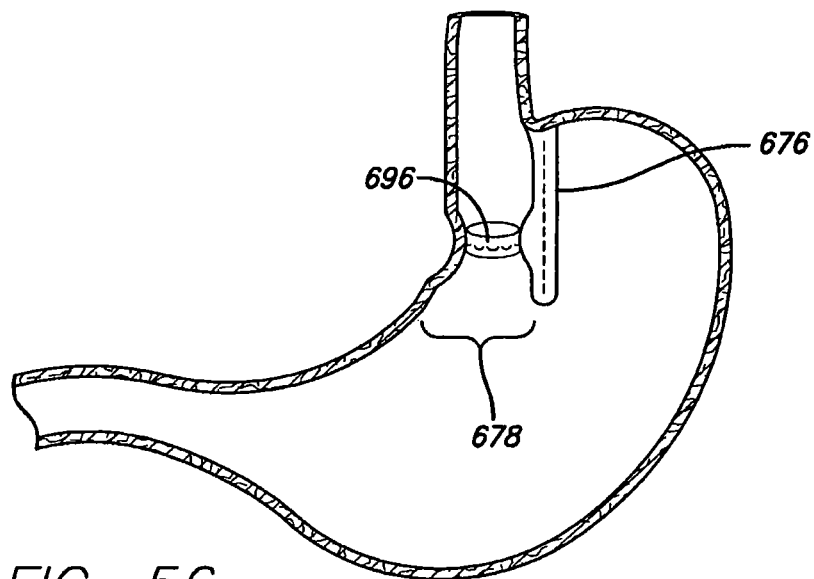


FIG. 56

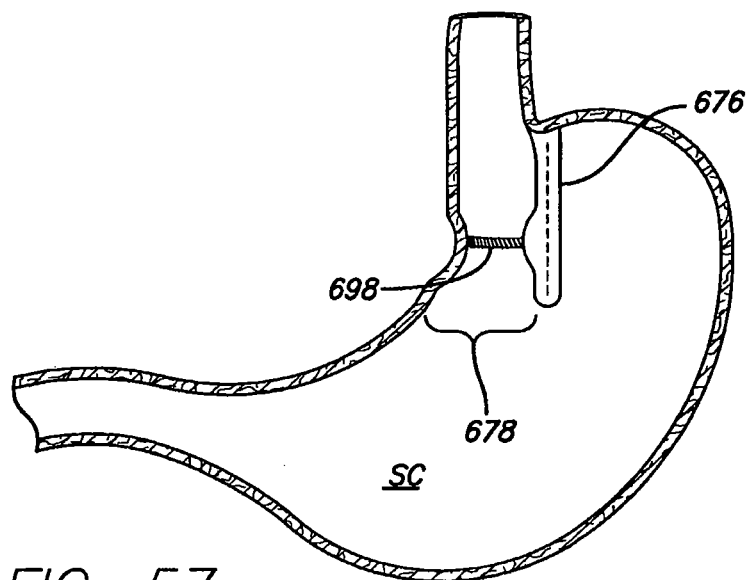
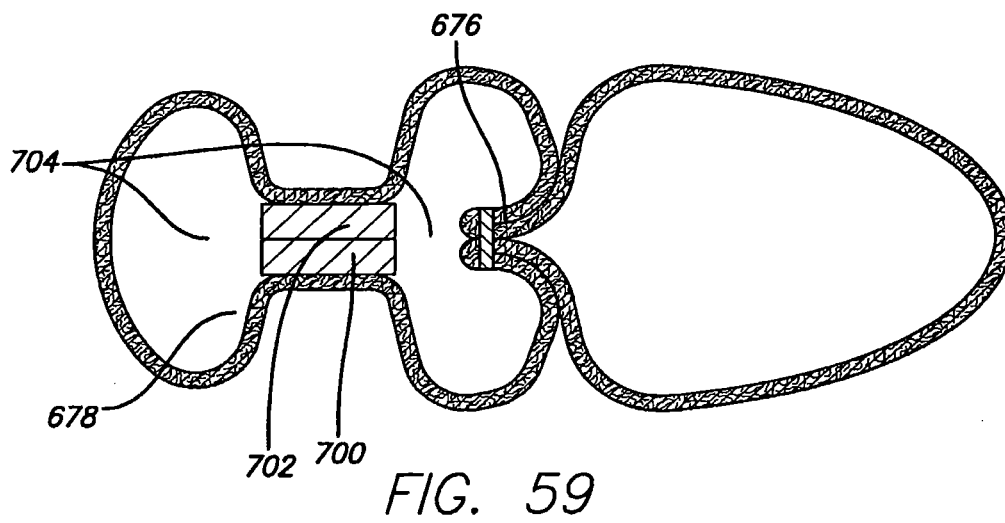
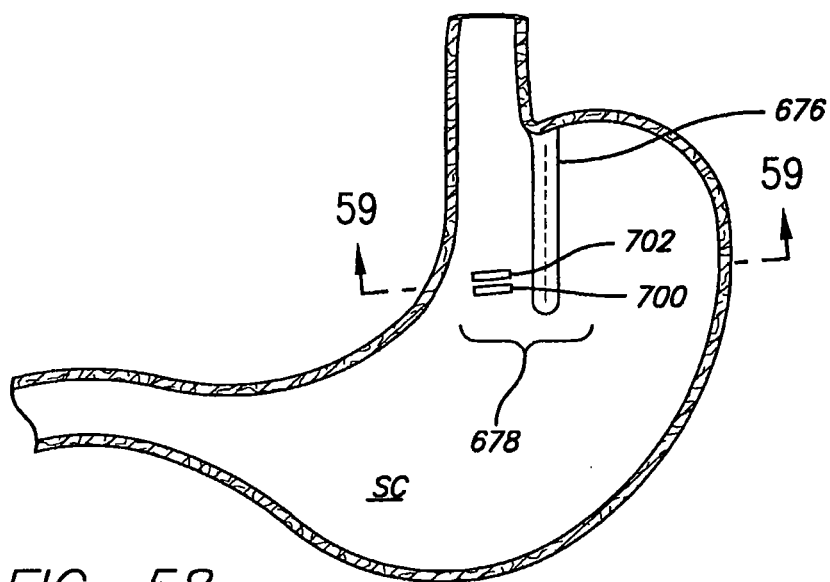
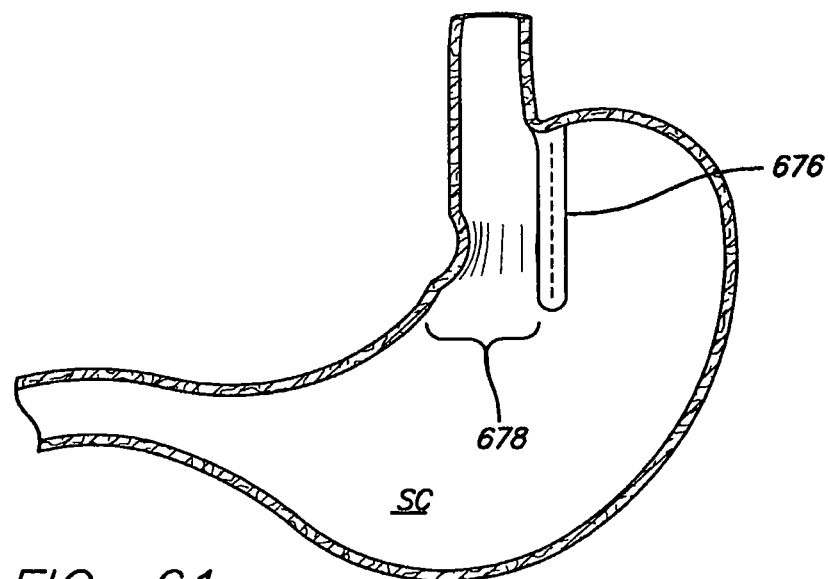
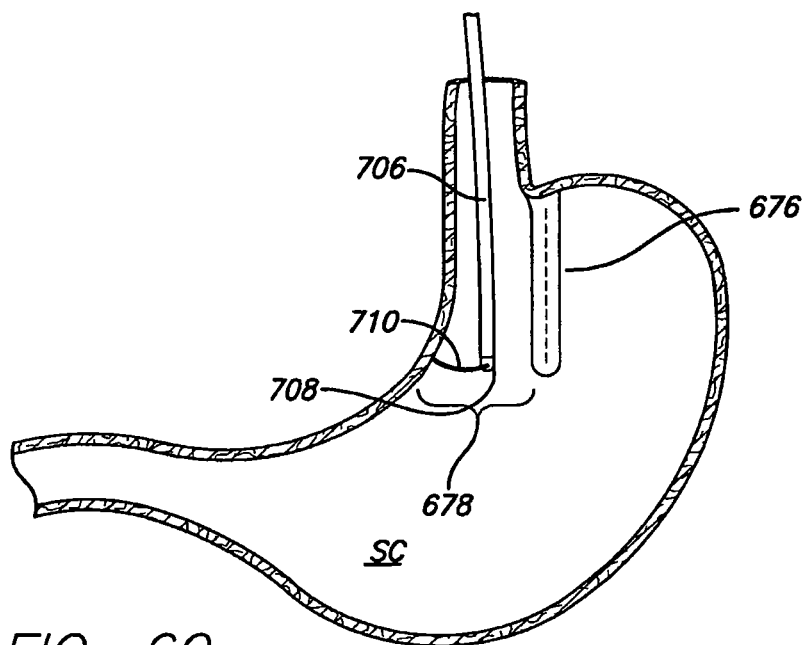
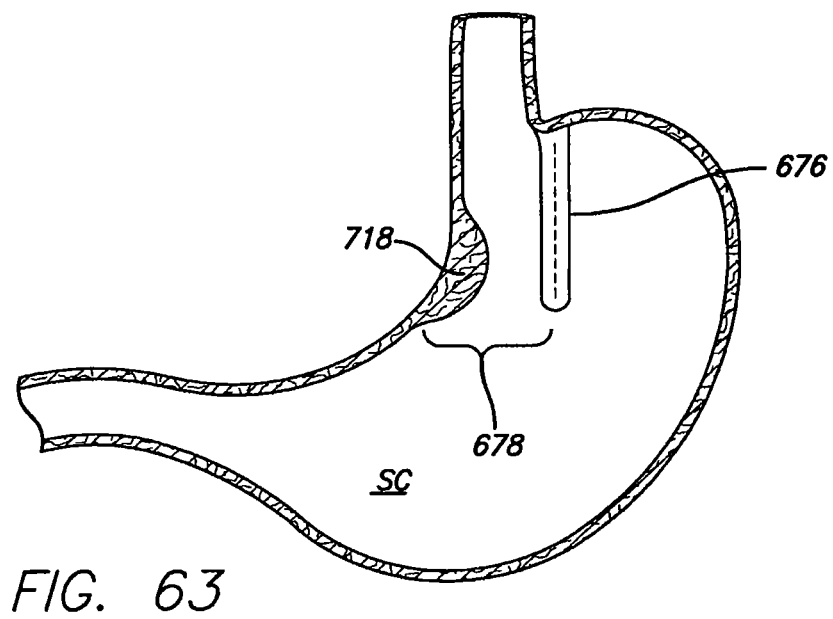
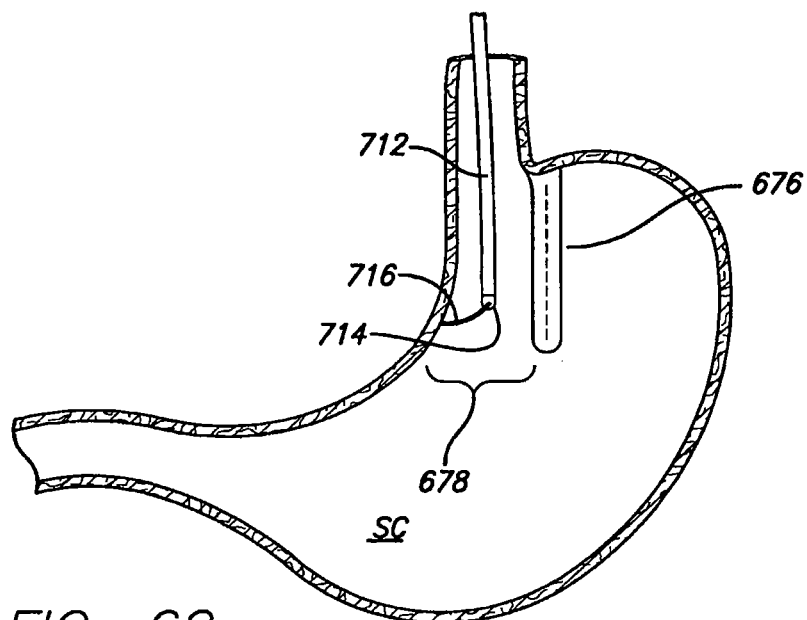


FIG. 57









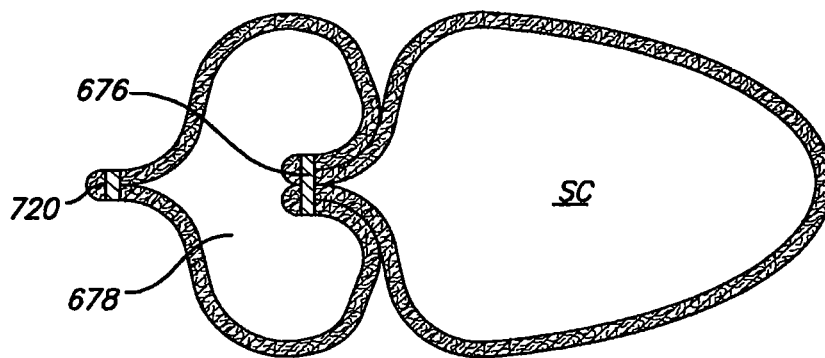


FIG. 64

# SINGLE FOLD DEVICE FOR TISSUE FIXATION

## CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of application Ser. No. 13/049,628 filed on Mar. 16, 2011, now issued as 8,357,174, which is a Divisional Application of application Ser. No. 11/107,382 filed on Apr. 15, 2005, now issued as U.S. Pat. No. 7,914,541 which is a continuation-in-part of application Ser. No. 10/686,326 filed on Oct. 14, 2003, now Issued as U.S. Pat. No. 7,097,650, which are herein incorporated by reference in their entireties.

## BACKGROUND OF THE INVENTION

### 1. Field of the Invention

The present invention relates generally to medical apparatus and methods. More particularly, it relates to devices and methods for approximating portions of a hollow body organ, particularly a stomach, intestine, or other region of the gastrointestinal tract, while affixing the tissue.

### 2. General Background and State of the Art

In cases of severe obesity, patients may currently undergo several types of surgery either to tie off or staple portions of the large or small intestine or stomach, and/or to bypass portions of the same to reduce the amount of food desired by the patient, and the amount absorbed by the gastrointestinal tract. The procedures currently available include laparoscopic banding, where a device is used to "tie off" or constrict a portion of the stomach, vertical banded gastroplasty (VBG), or a more invasive surgical procedure known as a Roux-En-Y gastric bypass to effect permanent surgical reduction of the stomach's volume and subsequent bypass of the intestine.

Typically, these stomach reduction procedures are performed surgically through an open incision and staples or sutures are applied externally to the stomach or hollow body organ. Such procedures can also be performed laparoscopically, through the use of smaller incisions, or ports, through trocars and other specialized devices. In the case of laparoscopic banding, an adjustable band is placed around the proximal section of the stomach reaching from the lesser curve of the stomach around to the greater curve, thereby creating a constriction or "waist" in a vertical manner between the esophagus and the pylorus. During a VBG, a small pouch (approximately 20 cc in volume) is constructed by forming a vertical partition from the gastroesophageal junction to midway down the lesser curvature of the stomach by externally applying staples, and optionally dividing or resecting a portion of the stomach, followed by creation of a stoma at the outlet of the partition to prevent dilation of the outlet channel and restrict intake. In a Roux-En-Y gastric bypass, the stomach is surgically divided into a smaller upper pouch connected to the esophageal inflow, and a lower portion, detached from the upper pouch but still connected to the intestinal tract for purposes of secreting digestive juices. A resected portion of the small intestine is then anastomosed using an end-to-side anastomosis to the upper pouch, thereby bypassing the majority of the intestine and reducing absorption of caloric intake and causing rapid "dumping" of highly caloric or "junk foods".

Although the outcome of these stomach reduction surgeries leads to patient weight loss because patients are physically forced to eat less due to the reduced size of their stomach, several limitations exist due to the invasiveness of the procedures, including time, use of general anesthesia, time and pain

associated with the healing of the incisions, and other complications attendant to major surgery. In addition, these procedures are only available to a small segment of the obese population (morbid obesity, Body Mass Index $\geq$ 40) due to their complications, leaving patients who are considered obese or moderately obese with few, if any, interventional options.

In addition to surgical procedures, certain tools exist for approximating or otherwise securing tissue such as the stapling devices used in the above-described surgical procedures and others such as in the treatment of gastroesophageal reflux disease (GERD). These devices include the GIA® device (Gastrointestinal Anastomosis device manufactured by Ethicon Endosurgery, Inc. and a similar product by USSC), and certain clamping and stapling devices as described in U.S. Pat. Nos. 5,403,326; 5,571,116; 5,676,674; 5,897,562; 6,494,888; and 6,506,196 for methods and devices for fundoplication of the stomach to the esophagus for the treatment of gastroesophageal reflux disease (GERD). In addition, certain tools, such as those described in U.S. Pat. Nos. 5,788,715 and 5,947,983, detail an endoscopic suturing device that is inserted through an endoscope and placed at the site where the esophagus and the stomach meet. Vacuum is then applied to acquire the adjacent tissue, and a series of stitches are placed to create a pleat in the sphincter to reduce the backflow of acid from the stomach up through the esophagus. These devices can also be used transorally for the endoscopic treatment of esophageal varices (dilated blood vessels within the wall of the esophagus).

There is a need for improved devices and procedures. In addition, because of the invasiveness of most of the surgeries used to treat obesity and other gastric disorders such as GERD, and the limited success of others, there remains a need for improved devices and methods for more effective, less invasive hollow organ restriction procedures.

## SUMMARY OF THE INVENTION

A system for tissue approximation and fixation is described which may be used to approximate tissue regions from within a hollow body organ, such as the stomach, esophageal junction, and other portions of the gastrointestinal tract. Generally, the devices of the system may be advanced in a minimally invasive manner within a patient's body, e.g., transorally, endoscopically, percutaneously, etc., to create one or several divisions or plications within the hollow body organ. Examples of placing and/or creating divisions or plications may be seen in further detail in U.S. Pat. No. 6,558,400; U.S. patent application Ser. No. 10/188,547 filed Jul. 2, 2002; and U.S. patent application Ser. No. 10/417,790 filed Apr. 16, 2003, each of which is incorporated herein by reference in its entirety. The system may comprise at least a tissue acquisition and folding device and a tissue stapling or fixation device, each of which may be used together as a single system.

The folder assembly may generally comprise, in part, a pod assembly which may be used to initially acquire and approximate the tissue to be folded. The pod assembly may comprise a first pod member and a second pod member, each of which may be independently articulatable to form a first compact configuration and a second larger, expanded configuration. Each of the pod members may be connected to respective first and second actuation rods on the distal end of a yoke member, which connects the pod members to an elongate working body or shaft. The working body itself may be comprised of a plurality of aligned link members which are adapted to provide some flexibility to the working body and which

defines a main lumen throughout a length of the working body as well as through the handle connected to a proximal end of the working body. Moreover, the working body may be covered by a sheath or a covering to enhance the lubricity of the shaft as well as to maintain the interior of the working body clear from body fluids and debris and seal the shaft to allow insufflation of the target organ. Various materials may be utilized for the sheath including various plastics, elastomers, latex, polyurethane, thermoplastics, e.g., PTFE, silicone, PVC, FEP, Tecoflex®, Pebax®, etc., so long as they are preferably biocompatible.

One or both of the pod members may additionally define a vacuum chamber or opening into which the tissue may be drawn within. The opening of the vacuum chamber may be slotted along a direction parallel to a longitudinal axis of the working body; alternatively, the opening may be defined a variety of shapes, e.g., oval, elliptical, etc., and furthermore may be offset such that it is defined transverse to the longitudinal axis of the working body. Adjacent to and preferably parallel with the vacuum chamber is a tensioning arm or member, which may have a length equal to that of the vacuum chamber. Alternatively, a length of the tensioning member may be less than or greater than that of vacuum chamber. The distal end of each pod member may have a flexible and/or atraumatic tip such as a blunt, rounded, or “bullet” tip, made from any number of polymers to facilitate the guidance of the pod assembly into the hollow body organ without damaging tissue along the way.

A guidewire may optionally be used with the folder assembly during initial deployment and positioning within the hollow body organ in a manner similar to a catheter for guiding the pod assembly to a predetermined position. The use of the guidewire may assist in initial placement of the device transorally, and it can also be exchanged through a lumen in the tip of one or both of the pod tips. Both of the first and second pod members may each be adapted to pivot on respective hinge members such that in a first compact configuration, the first and second pod members are immediately adjacent to one another. When desirably positioned within the hollow body organ, a vacuum force may be applied within one or both of the pod members such that tissue begins to enter within one or both of the vacuum chambers or openings. To assist in placement of the device, various indicators may be used. For instance, one or several indicators may be located directly on the device or indicators may be utilized with the device in relation to anatomical structures or landmarks. In one example, an orientation marker may be placed at a point on the distal portion of the device that is visible endoscopically and can be adjusted relative to structures such as the “z-line” of the gastroesophageal, i.e., the place where a change in color of the tissue from whitish (esophagus) to a salmon color (stomach) occurs delineating what is referred to as the squamocolumnar junction, i.e., the point where the lining changes from esophageal (squamous) to stomach (columnar). Then, in moving to a second expanded configuration, one or both of the first pod member and/or the second pod member may be translated via actuation rods into opposing radial directions from one another such that the opposing areas of tissue are approximated to create an overlap region. Once this overlap region has been desirably created, the fixation assembly may be advanced distally through the main lumen of the folder assembly and positioned upon exiting the main lumen to become clamped directly over the overlapped tissue. It is also within the scope of this disclosure to actuate the pods simultaneously, serially or singularly where only one fold of tissue is manipulated and fastened.

Vacuum tubes may be routed through the length, or a partial length, of the working body for communication with the pod assembly. The proximal ends of the vacuum tubes may be connected to one or more vacuum pumps. Furthermore, the vacuum tubes may utilize braided materials, e.g., stainless steel or superelastic materials such as Nickel-Titanium alloy, integrated throughout to prevent kinking or pinching of the tubes.

The fixation assembly comprises, in part, a manipulatable stapler assembly connected via a flexible shaft to a stapler handle. The stapler assembly itself generally comprises a staple cartridge housing within which one or more staples are housed. A corresponding anvil is positioned in apposition to the staple cartridge housing and may be used to provide a staple closure surface when tissue to be affixed is adequately positioned between the staple cartridge housing and the anvil. With the stapler assembly connected at the distal end of a flexible shaft, a handle is connected at the proximal end of the shaft. The handle itself may allow the surgeon or user to hold and manipulate the fixation assembly while articulating the stapler assembly between an open and closed configuration. Moreover, the configuration of the handle allows the surgeon or user to actuate the stapler assembly as well as deploy the staples from the staple cartridge housing.

In use, the fixation assembly may be advanced within the folder assembly main lumen with the fixation assembly configured in a closed configuration. To maintain an orientation, i.e., rotational stability, of the fixation assembly relative to the folder assembly and the approximated tissue, the fixation assembly may be configured to have a shape which is keyed to a cross-sectional area of the folder assembly main lumen. The keyed configuration helps to ensure that as the fixation assembly is advanced through the folder assembly, that the stapler assembly is optimally positioned to be clamped over the tissue for fixation.

When the stapler assembly is advanced and has exited the main lumen of the working body, the staple cartridge housing may be actuated into an open configuration when positioned between distally extending arm members of a yoke to receive the tissue folded between the pod members. The yoke arm members are configured such that when the stapler assembly is positioned therebetween, the stapler assembly is prevented from rotating or bending out of alignment for tissue affixation, i.e., the lateral stability of the stapler assembly is maintained relative to the yoke and the tissue. The stapler assembly may then be advanced distally over the folded tissue and clamped onto the tissue for deploying the staples. To avoid damaging tissue surrounding the pod assembly, one or several insertion indicators may be defined along a portion of flexible shaft of the fixation assembly, preferably near a proximal end of the shaft, to aid the user in knowing when the stapler assembly may be safely articulated while the fixation assembly is positioned within the working body, i.e., the longitudinal stability of the stapler assembly is maintained relative to the folder assembly. The indicators may be configured to align with a proximal end of the folder handle to correspondingly indicate, e.g., a position of the fixation assembly relative to the folder assembly when the stapler assembly may be opened, and/or how far distally the fixation assembly may be advanced relative to the folder assembly to engage the folded tissue, and when the devices are in a “safe to clamp” mode (e.g., in position around the tissue). Such positional indicators may utilize mechanical features, such as a stop or detent. In addition, the stapler assembly jaws may be spring-loaded open to assist insertion.

A tissue fixation device may also include a flexible shaft having a proximal end and a distal end, and a cartridge assem-

bly connected to the distal end of the elongated body. The cartridge assembly includes an acquisition member and a fixation member, wherein the fixation member includes a first jaw and a second jaw capable of pivoting relative to one another from a closed position to an open position. The acquisition member includes a vacuum pod fixed to at least one of the first and second jaws. When the first and second jaws are in the open position, the vacuum pod acquires and holds at least one fold of tissue between the first and second jaws, and the first and second jaws pivot into the closed position to plicate the tissue. The first jaw may be a staple cartridge that houses and ejects a plurality of staples, and the second jaw may be an anvil placed in apposition to the staple cartridge. A handle is disposed at the proximal end of the flexible shaft and includes at least one actuation mechanism adapted to articulate the cartridge assembly from the closed position to the open position, and to deploy a plurality of staples from the cartridge assembly.

Another tissue fixation device is a cross stapler device including a housing or distal frame containing a cartridge assembly and an anvil in apposition to the cartridge assembly. The contacting surfaces of the cartridge assembly and the anvil, which come into contact with one another when the device is actuated, lie in separate planes that are generally perpendicular to the longitudinal axis of the device. A vacuum opening is also disposed on the distal frame between the cartridge assembly and anvil. In use, the vacuum opening is able to acquire and hold at least one fold of tissue between the cartridge assembly and anvil, and cross stapler device is then actuated to fix the fold of tissue together with a plurality of staples. The cross stapler device is configured to form a pliated fold or flap of tissue that is perpendicular to the longitudinal axis of the device.

A method of treating tissue within a hollow body organ may include performing a primary procedure to reduce the volume of the hollow body organ, and then placing at least one plication to increase the success of the primary procedure. The at least one plication may be placed to reinforce the primary procedure, or may be placed to further reduce the volume of the hollow body organ. The at least one plication may also be placed to reduce an orifice created within the hollow body organ, or to close an orifice created within the hollow body organ.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a perspective view of a tissue folding and fixation assembly which may be advanced within a hollow body organ to reconfigure the tissue from within.

FIGS. 2A and 2B show side and top views, respectively, of a pod assembly which may be used to manipulate tissue.

FIGS. 2C to 2E show cross-sectional side views of rotatable valves which may be used control the vacuum force within the device.

FIGS. 3A and 3B show an end view of a pod assembly which has been translated with respect to one another while adhering tissue.

FIG. 3C shows an end view of a pod assembly in which a single pod member has been actuated with tissue adhered thereto.

FIG. 4 shows a representative illustration of the tissue overlap which is created by the translated pod assembly.

FIG. 5 shows an example of a cross-sectional side view of the tissue overlap where a stapler assembly has been articulated and clamped onto the tissue overlap.

FIG. 6A shows a partial assembly of the handle for the folder assembly.

FIG. 6B shows a detail view of an exploded assembly of anchoring mounts and a proximal portion of an actuation rod assembly.

FIG. 7 shows a side view of an alternative variation on a dual actuator folder assembly housing.

FIGS. 8A to 8C show side, end, and perspective views, respectively, of a link which may serve as a transitional link between the folder handle and the working body.

FIGS. 9A to 9C show side, end, and perspective views, respectively, of one variation of links which may be used to form at least part of the working body.

FIG. 9D shows an end view of a link having cross-sections of some of the various internal lumens which may be routed through the working body.

FIGS. 10A to 10C show side, end, and perspective views, respectively, of one variation of an end link which may be used as a terminal link of the working body.

FIG. 11 shows an end view of a link with the fixation assembly positioned within for advancement through the main lumen of the working body while maintaining a consistent orientation.

FIGS. 12A to 12C show top, cross-sectional side, and perspective views, respectively, of one variation of a yoke member.

FIGS. 12D and 12E show front and rear end views, respectively, of the yoke member of FIGS. 12A to 12C.

FIG. 13A shows a top view of a stapler cartridge assembly positioned between the arm members of the yoke.

FIGS. 13B and 13C show variations of the stapler assembly positioned between the yoke having varied open regions.

FIGS. 14A to 14C show top, end, and side views, respectively, of an alternative angled hinge member for use with a pod member.

FIGS. 15A to 15C show top and perspective views, respectively, of a variation of a yoke and hinge assembly.

FIGS. 16A to 16C show perspective views of a variation on a hinge device which may be adapted to angle a pod assembly in an offset configuration.

FIG. 17A shows a perspective view of one variation of the pod assembly with the top cover and optional basket insert removed for clarity.

FIG. 17B shows a perspective view of one variation of a top cover which may be used with the pod assembly.

FIG. 17C shows a cross-sectional view of an optional basket insert positioned within a vacuum chamber and a top cover secured over the chamber.

FIGS. 17D and 17E show another variation of FIGS. 17B and 17C, respectively, where the top cover and/or pod member may have serrations.

FIGS. 18A to 18D show side, end, bottom, and perspective views, respectively, of an optional basket insert which may be placed within the vacuum chamber of the pod assembly.

FIGS. 19A and 19B show side and top views, respectively, of another variation of the pod assembly where an angled pod assembly may be mounted on a distal end of the working body.

FIGS. 19C and 19D show rear and front views, respectively, of the pod members and the staple assembly of FIGS. 19A and 19B.

FIGS. 20A and 20B show side views of a variation of the stapler assembly in clamped and opened configurations, respectively.

FIGS. 21 A and 21 B show side views of a variation of a cam member which may be used to urge the stapler assembly open and close.

FIGS. 22A to 22C show cross-sectional side, front, and top views, respectively, of one variation of stapler assembly.

FIG. 22D shows a top view of the anvil of the stapler assembly.

FIG. 22E shows a side view of another variation of a stapler assembly having serrations defined along its clamping surfaces.

FIG. 23A shows a top view of one variation of staple pushers positioned over corresponding staples.

FIG. 23B shows a detailed perspective view of one example of a staple pusher.

FIG. 23C shows a perspective view of one example of a wedge which may be configured to slide within the cartridge housing.

FIGS. 24A and 24B show cross-sectional side views of one variation of a stapler handle and its associated controls.

FIGS. 25A and 25B show perspective views of another variation of the approximation device having an actively or passively curved working body.

FIG. 25C shows a detail view of the actuation handle of the device in FIGS. 25A and 25B.

FIGS. 25D and 25E show perspective and end views, respectively, of a variation of an end cap or seal which may be used to cap the handle of FIG. 25C.

FIG. 26 shows a perspective view of one variation in which an endoscope can be retroflexed to view the results or progress of the tissue approximation and/or fixation.

FIG. 27 shows a portion of a flexible shaft of a stapler assembly with several insertion indicators positioned through the main lumen of the handle of the folder assembly.

FIG. 28 shows a perspective view of another embodiment of a fixation assembly.

FIG. 29 shows an elevational view of a stapler assembly of the fixation assembly in a closed configuration.

FIG. 30 shows a perspective view of the stapler assembly in an open configuration.

FIG. 31 shows a partial cross-sectional view of the stapler assembly in the open configuration.

FIG. 32 shows an exploded view of a cross stapler device.

FIG. 33 shows a distal end of the cross stapler device.

FIG. 34 shows a partial perspective view of another embodiment of a cross stapler device.

FIGS. 35 through 42 show a cross-sectional view of one method of forming a gastric sleeve and an additional single fold of tissue near a distal stoma of the gastric sleeve to narrow the distal stoma.

FIG. 43 shows a schematic view of the single fold of tissue narrowing the distal stoma of the gastric sleeve.

FIG. 44 shows a schematic view of multiple plications placed within the stomach cavity, and single folds of tissue placed within the stomach cavity to narrow the outlets of the gastric sleeves created by the plications.

FIG. 45 shows a cross-sectional view taken along line 45-45 of FIG. 44.

FIG. 46 shows a schematic view of an intragastric band secured to the stomach wall and cinched to reduce the volume of the stomach, and multiple single fold plications placed around the intragastric band.

FIG. 47 shows a schematic view of an open proximal stoma of a longitudinal plication that is positioned too low in the stomach cavity.

FIG. 48 shows a schematic view of a plication placed to close the open proximal stoma of FIG. 47.

FIG. 49 shows a schematic view of a plication that is angled away from the lesser curve of the stomach.

FIG. 50A shows a cross-sectional view taken along line 50-50 of FIG. 49, with dual plications positioned in the distal stoma of the gastric sleeve.

FIG. 50B shows a cross-sectional view taken along line 50-50 of FIG. 49, with a dual fold plication positioned in the distal stoma of the gastric sleeve.

FIG. 51 shows a schematic view of a cross stapler device placing a plication within a gastric sleeve.

FIG. 52 shows a cross-sectional view taken along line 52-52 of FIG. 51 without the cross stapler device.

FIG. 53 shows a schematic view of two flaps of tissue placed within a gastric sleeve to act as a valve.

FIG. 54 shows a schematic view of a stapling device positioned to acquire and over-staple an existing longitudinal plication.

FIG. 55 shows a schematic view of a longitudinal plication within a stomach cavity and a laparoscopic band positioned around the outer surface of the stomach.

FIG. 56 shows a schematic view of a gastric band placed within a gastric sleeve to narrow the distal stoma.

FIG. 57 shows a schematic view of a surgical clip placed within a gastric sleeve to narrow the distal stoma.

FIG. 58 shows a schematic view of two magnets placed within a gastric sleeve to narrow the distal stoma.

FIG. 59 shows a cross-sectional view taken along line 59-59 of FIG. 58.

FIGS. 60 and 61 show a schematic view of a catheter delivering energy to the stomach tissue to shrink the tissue around a distal stoma of a gastric sleeve.

FIGS. 62 and 63 show a schematic view of a catheter delivering a bulking agent to the stomach tissue to narrow a distal stoma of a gastric sleeve.

FIG. 64 shows a cross-sectional view of a stomach cavity with an externally placed single fold of tissue near a distal stoma of a gastric sleeve.

## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

A system for tissue approximation and fixation is described which may be utilized for approximating tissue regions from within a hollow body organ, such as the stomach, esophageal junction, and other portions of the gastrointestinal tract. The system may be advanced within a body through a variety of methods, e.g., transorally, transanally, endoscopically, percutaneously, etc., to create one or several divisions or plications within the hollow body organ. At least two devices may be utilized as part of the system, a tissue acquisition and folding system and a tissue stapling or fixation system, although it is contemplated that both devices can be integrated into a single mechanism. Each of these devices may be configured to efficiently operate with one another to provide optimal methods and devices for at least acquiring, approximating, and stapling regions of tissue from within the hollow body organ in a minimally invasive manner.

Turning now to the figures, the system will first be described generally in which one variation of system 10 is shown in FIG. 1, which illustrates a perspective view of folder assembly 12 and fixation assembly 14. Folder assembly 12, which is described below in greater detail, may be comprised generally of pod assembly 16, which may be used to initially acquire and approximate the tissue to be folded. Pod assembly 16 may have a first pod member 18 and a second pod member 20, each of which may be independently articulatable to form a first compact configuration and a second larger, expanded configuration. Each of first and second pod members 18, 20 may be connected to respective first and second actuation rods 22, 24 on the distal end of a yoke member 26, as described in further detail below.

Pod assembly 16 may be located at the distal end of working body 28 which may be configured as a flexible shaft having one or several lumens defined through the length of the working body 28. The working body 28 may be covered by a sheath or covering 30 to enhance the lubricity of the shaft as well as to maintain the interior of the body 28 clear from body fluids and debris and provide a seal to allow insufflation of the target organ. Various materials may be utilized for sheath 30 including various plastics, elastomers, latex, polyurethane, thermoplastics, e.g., PTFE, FEP, silicone, PVC, Tecoflex®, Pebax®, etc., so long as they are preferably biocompatible.

A number of vacuum tubes 32 may also be routed through the length, or a partial length, of the working body 28 to pod assembly 16. The figure shows vacuum tubes 32 entering the working body 28 at its proximal end. Alternatively, vacuum tubes 32 may enter working body 28 at some distal point along the length of body 28 or vacuum tubes 32 may enter working body 28 through handle 34. In either case, vacuum tubes 32 may be positioned within one or several lumens defined through working body 28 and placed in fluid communication with respective first and second pod members 18, 20 to facilitate in vacuum actuation of tissue, as further described below. The proximal ends of vacuum tubes 32 may be connected to one or more vacuum pumps (not shown). Furthermore, vacuum tubes 32 may utilize braided materials, e.g., stainless steel, superelastic materials such as Nickel-Titanium alloy, integrated throughout to prevent kinking or pinching of the tubes 32. Such vacuum tubes 32 may also accommodate insertion of a snare or grasper type device that can be inserted once tissue is acquired to mechanically grasp the invaginated tissue, depending on the type of tissue manipulation desired. An example of a “gooseneck” snare by Microvena, Inc. which may be used with the vacuum tubes 32 is described in further detail in U.S. Pat. No. 5,171,233, which is incorporated herein by reference in its entirety.

The proximal end of working body 28 is operatively connected to handle 34. Also connected to handle 34 are first and second actuators 36, 38 which may be used to actuate first and second pod members 18, 20, respectively, from the first compact configuration to the second larger, expanded configuration. Each actuator 36, 38 may be actuated individually to control a corresponding pod member independently of the other pod member or may be actuated simultaneously, as described later herein. Main lumen 40 may be defined throughout the length of working body 28 and through handle 34 such that fixation assembly 14 may be advanced and withdrawn through the folder assembly 12. Fixation assembly 14 comprises, in part, stapler assembly 42 connected via flexible shaft 48 to a stapler handle 50. Stapler assembly 42 generally comprises staple cartridge 44, within which one or more staples are housed. Stapler assembly 42 may also have an optional tapered distal end to facilitate insertion of the device into or past tissue, as described in further detail below. Anvil 46 is in apposition to staple cartridge 44 and is used to provide a staple closure surface when tissue to be affixed is adequately positioned between staple cartridge 44 and anvil 46. With stapler assembly 42 connected at the distal end of flexible shaft 48, handle 50 is connected at the proximal end of shaft 48. Handle 50 may generally comprise a housing and grip 52 in apposition to actuation handle 54. Handle 50 allows for the surgeon or user to hold and manipulate fixation assembly 14 with grip 52 while articulating stapler assembly 42 between an open and closed configuration via actuation handle 54. Moreover, the configuration of handle 50 allows the surgeon or user to articulate stapler assembly 42.

When fixation assembly 14 is advanced within folder assembly 12, stapler assembly 42 is preferably in a closed

configuration. When stapler assembly 42 has exited working body 28, staple cartridge 44 may be articulated into an open configuration when positioned between yoke 26 to receive the tissue folded between pod members 18, 20. Stapler assembly 42 may then be advanced distally over the folded tissue and clamped close over the tissue for deploying the staples. To avoid damaging tissue surrounding pod assembly 16 and to facilitate proper stapling, one or several insertion indicator(s) 56 may be defined along a portion of flexible shaft 48 preferably near a proximal end of shaft 48, to aid the user in knowing when stapler assembly 42 may be safely articulated while fixation assembly 14 is positioned within working body 28. Indicators 56 may be configured to align with a proximal end of folder handle 34 to correspondingly indicate, e.g., a position of fixation assembly 14 relative to folder assembly 10 when stapler assembly 42 may be opened, and/or how far distally fixation assembly 14 may be advanced relative to folder assembly 10 to engage the folded tissue, etc. In addition to visual indicators, a mechanical indication, such as a stop or detent may be employed to give the operator a tactile indication of “safe to open” and “safe to clamp” device positions.

A brief description of the pod assembly 16 will be given in order to describe how the tissue may be manipulated by the devices described herein. A more detailed description will be given below. Side and top views of one variation of pod assembly 16 is shown in FIGS. 2A and 2B, respectively. Pod members 18, 20 may each be comprised of a vacuum chamber or opening 60 into which tissue may be drawn therewithin. A vacuum tube 76 may be seen in FIG. 2A leading to first pod member 18. The opening of vacuum chamber 60 may be slotted along a direction parallel to a longitudinal axis of the working body 28, or may be transverse to the parallel axis; alternatively, the opening may be defined a variety of shapes, e.g., oval, elliptical, etc. Adjacent to and preferably parallel with vacuum chamber 60 is tensioning arm or member 62, which may have a length equal to that of vacuum chamber 60. Alternatively, a length of tensioning member 62 may be less than or greater than that of vacuum chamber 60. The distal end of each pod member may have a flexible and/or atraumatic tip 64, 66 made from any number of polymers to facilitate the guidance of pod assembly 16 into the hollow body organ without damaging tissue along the way.

A guidewire may optionally be used with the folder assembly 12 during initial deployment and positioning within the hollow body organ in a manner similar to a catheter for guiding pod assembly 16 to a predetermined position. Accordingly, an optional guidewire lumen may be defined in one or both atraumatic tips 64, 66; as seen in tip 64, guidewire lumen 68 may be defined therein with guidewire 80 extending through from proximal guidewire opening 70 to distal guidewire opening 78. Proximal and distal guidewire openings 70, 78, respectively, may both be defined on, e.g., atraumatic tip 64, to enable exchange of the guidewire through one or both tips; however, guidewire openings 70, 78 may also be defined on other regions of pod members 18, 20 depending upon the type of exchange capability desired.

Both first and second pod members 18, 20 may each be adapted to pivot on respective hinge members 72, 74 such that in a first compact configuration, first and second pod members 18, 20 may be immediately adjacent to one another. As shown, first pod member 18 has a corresponding tensioning member 62 aligned adjacent to member 18 and second pod member 20 has a corresponding tensioning member 90 also aligned adjacent to member 20. In moving to a second expanded configuration, pod member 18 with tensioning member 62 and pod member 20 with tensioning member 90



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may be translated via actuation rods **22** into opposing radial directions from one another relative to yoke **26**, as shown in FIG. **2B**.

The vacuum force which may be used to draw in the tissue may be controlled through a number of various methods. One variation is illustrated in FIGS. **2C** to **2E**, which show how valves **82** may be integrated into handle **34** for controlling the vacuum force. As seen in the cross-sectional side view of FIG. **2C**, valve **82** may be configured to rotate and align such that vacuum lumen **84** comes into fluid communication with lumen **86**, which leads to working body **28**. Vacuum lumen **84** may be connected to a vacuum control unit (not shown), e.g., a standard luer assembly (QOSINA, model #99720), to allow for air to be drawn through lumen **86** and create the vacuum at the distally-located pod members. FIG. **2D** shows how valve **82** may be rotated by some degree, e.g., 45° relative to a longitudinal axis of handle **34**, such that the vacuum force is no longer in fluid communication with lumen **86**. FIG. **2E** shows how valve **82** may be further rotated, e.g., 90° relative to a longitudinal axis of handle **34**, such that lumen **86** is in fluid communication with venting lumen **88** to allow for venting of the assembly. A second valve, as shown, may be integrated in handle **34** to allow for the independent control of the vacuum force in the second pod member. Each of the vacuum lumens **84** may be fluidly connected to a common or independent vacuum pump. Moreover, rather than having two independently controllable valves **82**, a single valve **82** may be utilized to control the vacuum force in both pod members, depending upon the desired results. The above variations are intended to be illustrative and are not intended to be limiting in their scope of the disclosure in the various possible configurations and methods available for controlling the vacuum force.

FIGS. **3A** and **3B** show the movement of pod members **18**, **20** relative to one another in reconfiguring the surrounding tissue. FIG. **3A** shows an end view of pod members **18**, **20** which have been advanced while in a closed configuration into, e.g., a stomach, and positioned adjacent to a region of interior tissue to be reconfigured. When desirably positioned, a vacuum force may be applied within one or both pod members **18**, such that tissue begins to enter within one or both of the vacuum chambers or openings **60**, **92**.

The different linings of the stomach, which include the mucosal layer MUC, muscular layer ML, and serosal layer SL, are shown in cross-section. The vacuum force may be applied such that at least the mucosal layer MUC of opposing portions of tissue, e.g., an anterior wall AW and posterior wall PW, are drawn into vacuum chambers **60**, **92** and the tissue is sufficiently adhered to the pod members **18**, **20**. While the vacuum force is applied, pod members **18**, **20** may be translated away from one another in opposing direction such that the adhered tissue is drawn between each pod member **18**, **20** and respective tensioning member **62**, **90** such that at least two adjacent folds of tissue are created to form an overlap region of tissue, as shown in FIG. **3B**. Alternatively, rather than having both pod members **18**, **20** move opposite to one another, one pod member may be held stationary while the other pod member is translated radially. In addition, it may be desirable to acquire tissue and translate a first pod, and subsequently acquire tissue and translate a second pod as a separate step to enhance tissue acquisition and positioning. After the tissue has been acquired through any of the methods described above, the device may be curved or manipulated, as described in further detail below. The tissue may then be affixed through one of the methods as described herein.

Similarly, it may be desirable to actuate only one pod and tensioning member to acquire a single, longitudinal fold, for

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use in treatments such as GERD or to exclude certain portions of the wall of the body organ. Examples of other treatments are described in further detail in co-pending U.S. patent application Ser. No. 10/417,790, which has been incorporated by reference above. Accordingly, similar to the tissue acquisition in FIG. **31B**, FIG. **3C** shows how the device may be utilized for acquiring and tensioning a single layer of tissue. In such an acquisition, the vacuum force may be simply shut or turned off in one of the pod members, in this case, pod member **18** while the vacuum force in pod member **20** may remain activated.

FIG. **4** shows a representative illustration of the tissue overlap which is created by the devices, as described herein. The devices are removed for clarity to better illustrate the tissue overlap formation. FIG. **5** shows an example of a cross-sectional side view of tissue overlap **100** where staple cartridge **44** and anvil **46** have been articulated and clamped onto overlap **100** for stapling. When the tissue overlap **100** is created by folder assembly **12**, overlap **100** preferably includes an overlap of at least the muscular layer ML and serosal layer SL to ensure a secure anchoring platform for the staples or fasteners to maintain the durability of the tissue overlap **100**. A more detailed discussion may be found in U.S. patent application Ser. No. 10/188,547 filed Jul. 2, 2002 and entitled "Method And Device For Use In Tissue Approximation And Fixation", which is incorporated herein by reference in its entirety.

Folder Assembly

Folder assembly **12** may typically comprise a handle **34** at a proximal end of the assembly **12**, as described above. Handle **34** may comprise housing **110** which may enclose a pod actuation assembly within. FIG. **6A** shows a partial assembly of handle **34** to illustrate the internal mechanisms. As described above, first actuator **36** may be used to manipulate first pod member **18** from a first configuration to a second configuration. Pod manipulation may be achieved, in part, by having first actuator **36** connected via shaft **112** to transmit a torquing force to threaded carriage shaft **114**. The carriage shaft **114** is preferably free-floating, i.e., can translate longitudinally inside the shaft **112**. Proximal mount **116** may be free to rotate about the carriage shaft **114**, but it is preferably constrained to inhibit translation of mount **116** relative to the carriage shaft **114**. Distal mount **118** may be slidably positioned over carriage shaft **114**, typically by a threaded connection. This threaded connection maintains a fixed relative distance between the mounts so that the mounts and the carriage shaft **114** may translate longitudinally as a unit. Proximal mount **116** and distal mount **118** may be anchored to the proximal ends of the actuation rod and tubing member, which houses the actuation rod, as described further below. Each mount **116**, **118** and shaft **112** may be configured to be free-floating, i.e., translate longitudinally unconstrained, inside of shaft **112** within first actuation channel **120** to accommodate the lateral movement of working body **28** and the subsequent translational movement of the proximal ends of actuation rods within housing **110**. Stop **144**, e.g., a ring or shoulder defined upon shaft **114**, may be positioned proximally of mount **116** to prevent the longitudinal movement of mount **116** along shaft **114**. Mounts **116**, **118**, however, may be configured to maintain a fixed distance relative to one another when longitudinally translated as a unit. Corresponding mounts may be configured to translate along a second shaft (not shown) within second actuation channel **122** for a second actuation rod. Mounts **116**, **118** may thus translate as a unit until actuator **36** is rotated.

The handle mechanism **34** helps to ensure that relative or unwanted movement of the pods during flexing of the shaft of

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the folder in minimized or eliminated. Additionally, tubes **136**, as further described below, function so that the shaft of the device is not loaded during actuation. These tubes **136** help to support the actuation load, but still allow sufficient shaft flexibility.

As shown in FIG. 6B, which is a detail view of an exploded assembly of mounts **116**, **118** and their corresponding actuation rod assembly. Proximal mount **116** may have a rod anchoring region **130** defined along one side and distal mount **118** may have tubing anchoring region **132** defined along one side and collinearly with rod anchoring region **130**. Actuation rod **140** may be slidably positioned within tubing member **136** and configured to slide longitudinally therewithin when translated relative to tubing member **136** for actuating a pod member. Actuation rod **140** may be anchored to proximal mount **116** by securely positioning actuation rod anchor **142** within anchoring region **130**. Likewise, tubing member **136** may be anchored to distal mount **118** by positioning tubing anchor **138** within tubing anchoring region **132**. Each mount **116**, **118** may have collinearly defined openings **134** to accommodate rod tubing **136** and actuation rod **140** when they are secured within anchoring regions **130**, **132**. As actuator **36** is rotated, carriage shaft **114** is rotated about its longitudinal axis to urge mount **118** towards or away from mount **116**, as shown by the arrows, depending upon which direction carriage shaft **114** is rotated. When mounts **116**, **118** are urged towards one another, actuation rod **140** is forced to slide distally within and relative to tubing **136** to urge the pod member, e.g., into its expanded configuration. Similarly, when mounts **116**, **118** are urged away from one another, actuation rod **140** is forced to slide proximally within and relative to tubing **136** to urge the pod member, e.g., into its compact configuration.

As further seen in FIG. 6A, main lumen **40** may be defined through a length of housing **110** to accommodate insertion of the fixation assembly **14** therethrough. The proximal opening **128** of lumen **40** may be gasketed to allow for the insufflation of the hollow body organ using the device as well as to prevent the leakage of bodily fluids and particles. Distal opening **124** may likewise be gasketed and is further configured to accept a proximal end of working body **28**. The individual links **126** of one variation of the proximal end of working body **28** are shown in the figure to illustrate an example of the mating between working body **28** and housing **110**.

An alternative variation on the folder assembly housing is shown in dual actuator assembly **150** in FIG. 7. In this variation, a side view of housing **152** is seen in which a single actuator or lever **158** may be utilized to manipulate both pod members simultaneously. Lever **158** may be configured to rotate about pivot **160** to urge actuation link **162** to translate within actuation slot **164** to simultaneously manipulate both pod members rather than having two or more separate controls. The proximal end of working body **154** may be seen connected to housing **152** and vacuum tube **156** may be seen leading into working body **154** for communication with the folder assembly.

When lever **158** is depressed, actuation link **162** translates proximal linkage **155** within actuation slot **164**. Proximal linkage **155** is free to rotate about a pivot during flexure of the working body **154** and actuates proximal blocks **153** to slide longitudinally within channels **151**, which are defined through housing **152**. A spring or biased element **168** may be positioned within slot **164** to place a biasing force on link **162** and lever **158** such that the assembly maintains a neutral or fixed orientation, if desired. Proximal blocks **153** are connected to actuation rods **157** which may extend distally through distal blocks **159** and further into working body **154**.

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Distal blocks **159** may be pivotally connected to distal linkage **163**, which may be pivotally affixed to housing **152** via pivot **166** while allowing distal blocks **159** to translate within channels **151**. Tubing members **161** may be configured to allow passage of actuation rods **157** therethrough while remaining connected to distal blocks **159**. Although the specific configuration of this variation is shown and described, this is not intended to be limiting and is illustrative of one variation of a handle which allows for single activation and tunable mechanical advantage.

The working body **28**, which extends between the handle and the pod assembly located at the distal end of the working body **28**, may be comprised of a plurality of links or knuckles generally cylindrical in shape and positioned adjacently to one another, as shown and described above in FIG. 6A. A transition link or knuckle **170** is shown in FIGS. 8A to 8C, which show side, end, and perspective views, respectively, of a link which may serve as a transitional link between the handle and the length of the working body **28**. As seen in the side view of FIG. 8A, transition link **170** may have a proximally located cylindrically-shaped flange **172** with a diameter greater than a diameter of the body portion **176**. Flange **172** may serve to help anchor the working body **28** to the handle by fitting within a cavity defined in the handle and shaped to receive flange **172**. A transition portion **174** may taper a region of the link **170** down to body portion **176**. The end view in FIG. 8B shows main lumen **178** defined through the length of link **170**. Main lumen **178** may be shaped with parallel sides opposite to one another to allow fixation assembly therethrough in a specified configuration, as described below in further detail.

Although the transition link **170** is shown to be generally cylindrical in shape, it may alternatively be configured in a variety of shapes, e.g., ovalar, elliptical, etc. Transition link **170** may also range in diameter, e.g., 0.75 in. (about 1.90 cm), so long as it is wide enough to accommodate the insertion of fixation assembly **14** therethrough yet small enough to be inserted into the body, e.g., through the esophagus. Link **170** may also range in length, e.g., 1.125 in. (about 2.85 cm), depending upon the desired design characteristics. Moreover, transition link **170** may be made from a variety of materials, e.g., metals, plastics, etc., so long as it is biocompatible. For example, transition link **170** may be made from stainless steel, nickel-titanium alloys, or it may be molded from plastics and thermoplastics, e.g., polycarbonate resins such as Makrolon® (Bayer Aktiengesellschaft, Germany).

FIGS. 9A to 9C show side, end, and perspective views, respectively, of an example of a knuckle or link **180** which may be used to form at least part of the working body **28**. This link variation **180** may be made from a material similar to that of transition link **170**. It may also range in diameter, e.g., 0.69 in. (about 1.75 cm), so long as link **180** is wide enough to accommodate the insertion of fixation assembly **14** therethrough yet small enough to be inserted into the body, as above. Lumen **182** may be configured such that it is keyed to allow fixation assembly **14** to pass through in a specified configuration; thus, in this particular variation, lumen **182** is shown as having straight walls **196**, which may be parallel and opposite to one another. Link **180** may also define one or more routing channels **184** around the circumference of the link **180** to allow for the routing of various wires or tubes therethrough along a length of working body **28**. Link **180** shows a variation in which two routing channels **184** may be defined on opposing sides around the circumference. As further seen in FIG. 9A, link **180** may further define peripherally located actuator rod lumens **196** and additional routing lumens **188** in link **180** outside of lumen **182**. This variation

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shows at least two of each lumen **186**, **188** defined on opposing sides of link **180**, although they may be defined elsewhere around link **180** in other variations depending upon the number of lumens desired as well as spacing considerations.

FIG. 9B shows a side view of link **180** having least two protrusions **190** extending from a first surface **192** on either side of the periphery of link **180**. Protrusions **190** may extend from first surface **192** at a distance, e.g., 0.040 in. (about 0.10 cm), so that when multiple links are aligned with one another, protrusions **190** abut the second surface **194** of an adjacent link, as shown in FIG. 9C. When multiple links are aligned, lumen **182**, as well as actuator rod lumen **186** and additional routing lumen **188** may be aligned with adjacent links to form the overall main lumen **40** and actuator rod lumen, as described above. Alternatively, overall flexibility of the device may be achieved by a single structure that contains axial slots along its length, such as that shown in U.S. Pat. No. 5,685,868, which is incorporated herein by reference in its entirety. Similarly, the working body may be formed of a single piece, flexible component, such as a polymer extrusion and/or multi-lumen co-extruded design, a braid, or other such known materials.

FIG. 9D shows an end view of link **180** in one variation where actuation rod **198** is routed through actuator tubing member **202** and both may be disposed within actuator rod lumen **186** such that both extend through a length of working body **28**. Vacuum tubes **200** may also be positioned within routing channels **184** and the entire assembly may be covered by sheath or lining **204**, which may extend along at least a portion of working body **28**, and preferably over the entire length of working body **28**. Sheath or lining **204**, as mentioned above, may be used to enhance the lubricity of the working body **28** as well as to maintain the interior of the body **28** clear from body fluids and debris and to provide sealing to enable insufflation of the target area. Various materials may be utilized for sheath **204** including various plastics, elastomers, latex, polyurethane, thermoplastics, e.g., PTFE, silicone, PVC, FEP, Tecoflex®, Pebax®, etc., so long as they are preferably biocompatible. Moreover, sheath **204** may also utilize braided materials integrated throughout to increase tensile, compressive, and/or torsional strengths of sheath **204** as well as to provide for resistance against kinking or pinching between individual links or when working body **28** is flexed.

FIGS. 10A to 10C show side, end, and perspective views, respectively, of one variation of end link **210**, which may be utilized as the terminal or final link of working body **28**. End link **210**, much like links **180**, may define a keyed lumen **212**, routing lumens **214**, and actuator rod lumen **218**. Lumen **216** may also be defined and it may be counterbored to accommodate a mechanical fastener for connecting the yoke member. As the terminal link, actuator tubing member **202** may be terminated and attached to end link **210** at lumen **218** while allowing the actuator rod to extend through and beyond lumen **218** for attachment to the pod assembly. Side and perspective views in FIGS. 10B and 10C further show detent **222**, which may be defined along the end surface of link **210** for receiving and/or engaging the yoke member. Moreover, end link **210** may be made from the same or similar materials as described above for the other links. However, end link **210** is preferably made from a material such as a metal, e.g., stainless steel, or polycarbonate, which may withstand forces generated during pod and tissue manipulation. The end link **210**, or a similar or additional link, may also be used to terminate any covering placed over the working body **28** as heretofore described in FIG. 9D.

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FIG. 11 shows an end view of link **180** with staple cartridge **44** and anvil **46** of fixation assembly **14** positioned within lumen **182** for advancement through working body **28**. As seen, lumen **182** may be configured such that it is keyed to allow fixation assembly **14** to pass through in a specified orientation. Walls **196**, which may be parallel and opposite to one another, may thus be sized and configured to prevent fixation assembly **14** from rotating about its own longitudinal axis within lumen **182** during advancement and deployment from the main lumen. Maintaining fixation assembly **14** in a predetermined orientation relative to working body **28** and pod assembly **16** also helps to ensure that when staple cartridge **44** and/or anvil **46** are actuated to open for clamping over folded tissue, a known orientation of fixation assembly **14** relative to the folded tissue is maintained for tissue fixation. Other configurations for keying lumen **182** to fixation assembly **14** may be available in other variations; the shape of lumen **182** and the cross-sectional shape of fixation assembly **14** are not intended to be limiting but are merely illustrative of one possibility of creating and/or configuring a keyed orientation between the two assemblies.

A yoke member may be positioned at the terminal end of working body **28** for holding and maintaining pod assembly **16**. FIGS. 12A to 12C show top, cross-sectional side, and perspective views, respectively, of yoke **230**. Generally, yoke **230** may be comprised of first arm member **232** and second arm member **234** extending in parallel to one another from a base member **242**, which may be attached via proximal surface **244** to end link **210** of working body **28**. Yoke **230** may terminate at each arm member **232**, **234** in first and second pivot regions **236**, **238**, respectively, about which the pod assembly **16** may be manipulated. First and second arm members **232**, **234** may further extend longitudinally with an overall length of about, e.g., 2 in. (about 5 cm), to create open region **240** between the arm members **232**, **234**. First and second arm members **232**, **234** may also be tapered along their lengths to facilitate insertion of yoke **230** within a tissue region. The opposing sides of each arm member **232**, **234**, which in part defines open region **240**, may be parallel to one another and are spaced apart, e.g., at 0.40 in. (about 1.0 cm), to provide clearance for stapler assembly **42** to be advanced therethrough. Furthermore, the open sides of region **240** may provide adequate clearance for stapler assembly **42** to be opened for advancement over tissue to be affixed while arm members **232**, **234** help to maintain the orientation of stapler assembly **42** relative to yoke **230** and working body **28**.

The actuation rods for manipulating pod assembly **16** may extend through yoke **230** via first and second actuation rod channels **246**, **248**, which may be seen in the perspective view of yoke **230** in FIG. 12C. A portion of actuation rod channels **246**, **248** may be slotted or grooved and open along an outer surface of each of arm members **232**, **234** to allow actuation rods to extend past the outer surface during pod manipulation. FIGS. 12D and 12E show front and rear end views, respectively, of yoke **230** to provide a detail view of actuation rod channels **246**, **248** and open region **240**.

As mentioned above and as shown in the top view of stapler cartridge/yoke assembly **250** in FIG. 13A, each arm member **232**, **234** may be parallel to one another and spaced apart to provide clearance for stapler assembly **42** to be advanced therethrough. The arm members **232**, **234** may function as guide surfaces **252**, **254**, respectively, to maintain stapler assembly **42** oriented in a predetermined configuration relative to yoke **230**. Furthermore, open region **240** may provide adequate clearance for stapler assembly **42** to be opened prior to advancement over tissue while guide surfaces **252**, **254** help to maintain the orientation of stapler assembly **42** relative

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tive to yoke **230** and working body **28**. Additionally, as shown in FIG. **13A**, clearance slots (open region **240**) may function to provide clearance for an endoscope or other tool, that can be inserted and advanced or retroflexed to view the working device, as shown below in further detail. To assist in alignment of the stapler assembly **42** to the target tissue, it may be desirable to vary the length of the open region **240**. As further shown in FIG. **13B**, open region **240** may be configured with a stop, cover, or extension **256** located adjacent to anvil **253** to constrain any transverse or lateral movement of anvil **253** while facilitating movement of cartridge assembly **251**. Alternatively, if anvil **253'** is configured to move, stop or extension **258** may be configured adjacent to cartridge assembly **251'** to constrain any transverse or lateral movement of cartridge assembly **251'** while facilitating movement of anvil **253'**, as shown in FIG. **13C**.

From the distal end of each arm member **232**, **234** of yoke member **230**, a hinge member may be connected pivotally and extend distally where it may be again pivotally connected to a pod member. An alternative angled hinge member **260** may be seen in FIGS. **14A** to **14C**, which show top, end, and side views, respectively. Angled hinge **260** may have a proximal portion **262** connected to a distal portion **264**, which may be angled with respect to either or both side surface **270** and top surface **272** of proximal portion **262**. A yoke-hinge pivot **266** may be defined at a proximal end of proximal portion **262** for pivotal connection to first pivot **236** located on yoke **230**. Similarly, a hinge-pod pivot **268** may be defined at a distal end of distal portion **264** for pivotal connection to a pod member. Additionally, actuator rod channel **274** may be optionally defined along at least a portion of proximal portion **262** to provide a opening or space for placement of an actuator rod. A second hinge member, which may mirror the configuration of angled hinge **260**, may be configured for connection to second hinge **238** of yoke **230** for connection to a second pod member. Moreover, angled hinge member **260** may be made from any variety of metals or thermoplastics, as described above.

Alternatively, a variation of a yoke/hinge assembly **280** may be utilized, as shown in the top views of FIGS. **15A** and **1513**. In this variation, yoke/hinge assembly **280** may be configured to flex via one or several additional pivots along its length. Additional ramp members **286**, **286'**, **290**, **290'**, which may be extension members of yoke **282** having pivoted regions at both proximal and distal ends, may be joined via pivots **284**, **284'**, **288**, **288'**, respectively, to one another to form elongated arms. Hinge members **294**, **294'** may be connected via pivots **292**, **292'**, respectively, to ramp members **290**, **290'**, respectively, and have pivots **296**, **296'** located at their distal ends for connection to pod members.

Hinge members **294**, **294'** may be actuated to an expanded configuration, as shown in FIG. **15A**, and yoke/hinge assembly **280** may also be configured to flex via tensioning members (not shown) positioned within a lumen or slot defined along the length of assembly **280** in one or both arms. These tensioning members may be actively manipulated by the user from their proximal ends. Thus, assembly **280** may be flexed to have a bend radius, as shown in the example of FIG. **15B**, to allow access to various regions within the hollow body organ as well as to affix various configurations of tissue. Alternatively, assembly **280** may also be passively flexed by contact against tissue or via an external device, such as a mandrel, a gripping tool, or endoscopes configured to flex the assembly **280**. FIG. **15C** shows an example of a compact configuration of assembly **280** which may be utilized for deployment within a body.

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FIGS. **16A** to **16C** show yet another variation on a hinge device which may be adapted to actively angle the pod assembly in an offset configuration. The working body, as well as vacuum tubes and other features, have been omitted only for the sake of clarity in these views. FIG. **16A** shows a perspective view of offset pod assembly **300** in a "straight" configuration where first pod member **302** and second pod member **304** are in a compact or deployment configuration. FIG. **16B** shows an example of offset pod assembly **300** in an expanded configuration where first and second pod members **302**, **304**, respectively, may be actuated to spread apart from one another. First tensioning member or arm **306** may be seen as being part of first pod member **302** and second tensioning member or arm **308** may be seen as being part of second pod member **308**.

Offset pod assembly **300** also includes variations on first and second hinge members **310**, **312**, respectively, which may have respective first and second actuation slots **322**, **324** defined longitudinally along a portion of their respective hinge members **310**, **312**. First actuation linkage **314** may be pivotally connected at its distal end to first pod member **302** and pivotally connected to first hinge member **310** at its proximal end via pivots **318**. The proximal end of actuation linkage **314** may also be configured to translate within first actuation slot **322** when urged. Likewise, second actuation linkage **316** may be pivotally connected at its distal end to second pod member **304** and pivotally connected to second hinge member **312** at its proximal end via pivots **320**. Also seen are first and second vacuum openings **326**, **328**, respectively, for acquiring tissue to be approximated, and first and second vacuum passages **330**, **332**, respectively.

FIG. **16C** shows offset pod assembly **300** having been urged into its offset configuration. As shown, the proximal end of first actuation linkage **314** has been translated distally within first actuation slot **322** and the proximal end of second actuation linkage **316** has also been translated distally within second actuation slot **324**. Each linkage **314**, **316** may be translated a distance,  $d$ , via actuation rods to rotate first and second pod members **302**, **304** about their respective pivots such that pod members **302**, **304** may be offset at an angle,  $\alpha$ , relative to a longitudinal axis of the working body. From this offset configuration, tissue may be approximated and affixed at various angles. Alternatively, the pod members **302**, **304** may also be configured to be passively flexed by contact against tissue or via an external device, including any of the tools described above. Although both pod members **302**, **304** are shown in this illustration as having been offset at similar angles, a single pod member may be alternatively actuated to become offset relative to the other pod member. Furthermore, both pod members may also be offset at various angles depending upon the desired tissue configuration; moreover, each pod member may be also independently offset at its own angle, again depending upon the tissue configuration. These examples are merely intended to be illustrative and are not intended to be limiting.

The pod assembly itself may be seen in greater detail in the perspective view of FIG. **17A**. As shown, the pod member may have an elongated vacuum chamber **340**. A top cover and an optional basket insert have been removed for clarity. The vacuum chamber **340** may be in fluid communication via vacuum tubes **200** which may be connected to a vacuum pump (not shown) at its proximal end and to vacuum chamber **340** at its distal end. Tensioning member or arm **342** may extend longitudinally adjacent to vacuum chamber **340** while forming a gap between the two through which the tissue may be drawn. The tensioning member **342** may extend along the entire length of the pod member and beyond or it may extend

just partially. Alternatively, in other variations, tensioning member **342** may be omitted entirely. In either case, a distal tip of the tensioning member **342** is preferably configured to be atraumatic, e.g., blunted, rounded, or it may have a separate soft tip attached and/or may be shaped or made of a material to conform to the distal esophagus and/or proximal stomach to allow ease of insertion and lessen trauma once in place.

A pivot **344** may be configured at the proximal end of the pod member for attachment to a hinge member. The distal end of the pod member may also have a tapered flexible tip **346** attached thereto. This tip **346** may be configured to have an atraumatic tip **354** to facilitate deployment of the device with minimal damage to the tissue. Flexible tip **346** may be made from any variety of biocompatible polymers and elastomers. Flexible tip **346** may also define a guidewire lumen **348** extending from a distal guidewire opening **350** at atraumatic tip **354** to proximal guidewire opening **352** located proximally on flexible tip **346**. As mentioned above, a guidewire may optionally be used to guide the pod members during initial deployment and positioning within the hollow body organ in a manner similar to a rapid-exchange (RX) type catheter. Accordingly, an optional guidewire may be passed through guidewire lumen **348** and subsequently removed, if desired. A flat mating surface **356** may also be defined along the side of flexible tip **346** to allow for a compact configuration when the second pod member is positioned adjacently. Tip **354** may be optionally formed of a radio-opaque material or imbued with radio-opaque capabilities.

A top cover **372** which defines opening **374**, as shown in FIG. **17B**, may be secured over vacuum chamber **340**. An undercut **358** may be defined around opening **374** to help aid in mechanically adhering any tissue which may be drawn into opening **374**. Opening **374** is shown as being slotted; however, it may be formed into an elliptical shape or various other shapes so long as an adequate opening is available for adhering a sufficient amount of tissue therewithin or thereto. Alternatively, rather than a single opening **374**, multiple smaller openings may be defined over top cover **372** so long as an adequate area is available for adhering tissue thereto. An optional mesh-like insert may be positioned within vacuum chamber **340** to help prevent the vacuum chamber from becoming clogged by tissue.

Turning to FIGS. **18A** to **18D**, an optional basket insert **360** is shown in side, end, bottom, and perspective views, respectively. Basket insert **360** may be placed within vacuum chamber **340** to provide for an optimized mesh surface through which a vacuum force may be applied to the tissue. Overall dimensions of basket insert **360** may vary so long as it may be securely positioned within vacuum chamber **340**. An example of insert **360** dimensions is 1.3 in. (about 3.3 cm) in length and 0.3 in. (about 0.8 cm) in width. Basket insert **360** may also be made from a variety of materials, e.g., stainless steel, provided that the tensile strength is sufficient to withstand the various forces generated.

Basket insert **360** may have basket walls **362** forming a mesh-like vacuum chamber **370** with flange **364** surrounding the edges of one open side of insert **360**. Each of the basket walls **362** may define a plurality of openings therethrough and the bottom surface of basket walls **362** may also define a plurality of supports **366** positioned in-between openings **368**. These supports **366** may be configured to space each of the basket walls **362** away from the walls of vacuum chamber **340**, as shown in FIG. **17C**, which shows a cross-sectional view of basket insert **360** positioned within vacuum chamber **340** and top cover **372** placed over the chamber **340**. Plenum **376** may thus be defined around the entire basket insert **360**,

or a portion thereof, between basket walls **362** and vacuum chamber **340** via the spacing provided by supports **366** and flange **364**. The open plenum **376** allows a vacuum force to be applied to the tissue while preventing the tissue from clogging the vacuum chamber **340**.

Alternatively, rather than utilizing a separate basket insert **360** for placement within vacuum chamber **340**, the interior surface of vacuum chamber **340** may be textured, channeled, labyrinthed, or interdigitated to increase the surface area for vacuum adherence in the same manner as basket insert **360**. Moreover, mechanical tines or teeth may be formed within basket insert **360** or within vacuum chamber **340** to facilitate additional mechanical adherence of tissue within the pod member. Another alternative may utilize a snare-like wire or member positioned within vacuum chamber **340** around opening **374**. In such a variation, once tissue has been drawn through opening **374**, the snare may be drawn tightly around the adhered tissue.

Moreover, one or both pod members may also incorporate a number of other methods to facilitate tissue movement and/or adherence to the respective pod member. For instance, FIGS. **17D** and **17E** show the top cover **372** and cross-sectional view of basket insert **360**, respectively, of FIGS. **17B** and **17C** with the addition of serrations **341**. These serrations **341** are shown as being defined along a length of cover **372**; however, they may alternatively be defined around the opening **374** or in a number of various other configurations depending upon the desired results. Furthermore, serrations **341** are illustrated as protrusions but any variations or configurations of serrations **341** may also be utilized in other variations of the device.

FIGS. **19A** and **19B** show another variation of the pod assembly where angled pod assembly **380** may be mounted on a distal end of working body **382**. As shown, first and second pod members **384**, **386**, respectively, may be configured to extend angularly via angled hinges **260**. Also shown are vacuum tubes **388** extending between pod members **384**, **386** and working body **382**. The figures also show the positioning of staple cartridge **44** and anvil **46** opened for clamping onto folded tissue, which is not shown for clarity. FIGS. **19C** and **19D** show rear and front views of pod members **384**, **386** and staple cartridge **44** and anvil **46**.

#### Fixation Assembly

The fixation assembly, as mentioned above, may be delivered through the main lumen of the folder assembly for deployment over tissue which has been approximated into a folded configuration. One variation of a stapler which may be used with the folder assembly described herein is described in detail in U.S. Pat. No. 4,610,383 (Rothfuss et al.), which is incorporated herein by reference in its entirety. Another variation of a stapler assembly **390**, which is positioned at the distal end of the fixation assembly, is shown in side views in FIGS. **20A** and **20B**. Generally, stapler cartridge **392** may be pivotally connected via pivot **396** to the end of flexible shaft **398**. Anvil **394** may be configured to remain stationary relative to flexible shaft **398** while stapler cartridge **392** may be manipulatable into an open and closed configuration with respect to flexible shaft **398** and anvil **394**. As seen, stapler cartridge **392** and/or anvil **394** may optionally incorporate a tapered end **411** positioned at a distal end of either cartridge **392**, anvil **394**, or both. Tapered end **411** may be fabricated of any of the polymers or other materials described herein and is preferably atraumatic to facilitate dilation or insertion past tissue. To manipulate stapler cartridge **392** to open and close, a circular or disk-shaped cam **400** may be pivotally attached about rotational pivot **402** located on the side of the proximal end of stapler cartridge **392**. As seen in the detail view of cam

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400 in FIG. 21A, actuation wires or cables 404, 406 may be wound about cam 400 such that when cable 404 is pulled, cam 400 is urged to rotate about rotational pivot 402 in the direction of arrow 408. Actuation cables 404, 406 may be manipulated from their proximal ends by the user. As cam 400 is rotated in direction 408, a portion of anvil 394 may be engaged by cam 400 thereby forcing stapler cartridge 392 to pivot into an open configuration, as shown in FIG. 20B, when cam 400 is fully rotated, as in FIG. 21 B. Cam 400 may be made into other shapes, e.g., oval, elliptical, etc., depending upon the desired design characteristics. One cam 400 may be utilized, as shown; however, an additional cam may also be affixed on the opposite side of stapler cartridge 392 such that dual cams are configured to open and close simultaneously in parallel. Alternatively, in the same device, the location of stapler cartridge 392 and anvil 394 may be reversed (e.g. anvil 394 may be configured to move toward cartridge 392) depending on the location of the desired target and clearance desired.

Detailed views of the stapler assembly is shown in FIGS. 22A to 22D. FIGS. 22A to 22C show cross-sectional side, front, and top views, respectively, of stapler assembly 410. Cartridge housing 412 generally houses a plurality of staples 414 which may be aligned adjacently to one another in one or more rows. The distal ends of both cartridge housing 412 and anvil 422 may be configured to be atraumatic, e.g., blunted, rounded, etc., to the tissue to be affixed. Moreover, cartridge housing 412 and anvil 422 may be configured such that their cross-sectional shape is keyed to the main lumen of the folder assembly so that the orientation of the cartridge housing 412 is maintained relative to the folder assembly, as described above.

FIG. 22C shows a top view of cartridge housing 412 wherein four rows of staples 414 may be aligned. Other variations of cartridge housing 412 may utilize fewer or greater than four rows of staples 414. To deploy staples 414 from cartridge housing 412, two wedges 416, 416', which may be offset or staggered from one another, may each be pulled proximally through cartridge housing 412 via staple actuation wire 420. Wedges 416, 416' may be adjacently positioned to one another but are preferably staggered such that the staples are deployed in a sequenced deployment order. Staple actuation wire 420 may be manipulated via its proximal end by the user when staples 414 are to be deployed out of cartridge housing 412 into the tissue.

Staples 414 may be deployed through staple apertures 418 defined over the surface of cartridge housing 412 in apposition to staple closure surface 424 of anvil 422. As the staggered wedges 416, 416' are pulled proximally, each wedge 416, 416' may engage one or more rows of staples and urge them through staple apertures 418, as shown in FIG. 22A, and through the tissue until they are engaged in corresponding staple detents 426, as shown in FIG. 22D. As further shown in FIG. 22D, which shows a top view of staple closure surface 424 of anvil 422, each staple detent 426 preferably corresponds to the distal ends of each staple 414.

As described above, cartridge housing 412 and/or anvil 422 may be configured to be atraumatic, e.g., blunted, rounded, etc.; however, it may be desirable to serrat or otherwise roughen the outside edges of both or either the cartridge 412 and/or anvil 422 to ensure full tissue capture upon clamping of the two surfaces. A variation of the stapler assembly 410 is shown in FIG. 22E, which shows serrations 428 defined along the lengths of cartridge 412 and anvil 422. Serrations 428 may be optionally defined along only one of cartridge 412 or anvil 422 and it may also be defined only partially along the length.

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Alternatively, other projections or protrusions, such as spears, may be utilized. In yet another alternative, rather than utilizing projections or serrations 428, the surfaces of cartridge 412 and/or anvil 422 in contact with the tissue may simply be roughened or sharpened to facilitate serrating or roughening the contacted tissue or may employ absorptive materials in the form of pads, coatings or covers to facilitate traction. Such pads, covers or coatings may be formed of cotton, Goretex®, polyester, Velcro, etc., and may remain on the surface of the cartridge once staples are delivery, or alternatively may be transmitted with the staples to remain with the tissue affixed thereby.

To facilitate the deployment of the staples 414 as wedges 416, 416' are urged through cartridge housing 412, staple pushers 430 may be utilized. As shown in FIG. 23A, which is a top view of one variation of staple pushers 430 positioned over corresponding staples 414, a single staple pusher 430 may be configured to engage two staples 414 in adjacent rows. When a wedge contacts a staple pusher 430, two adjacent staples 414 may be fired sequentially. FIG. 23B shows a detailed perspective view of one example of a staple pusher 430. In this variation, staple pusher 430 may be comprised of one or more sloped cam surfaces 432, 434 for slidably engaging a wedge. As a wedge engages a cam surface, it may push staple pusher 430 down towards staples 414 as pusher 430 is guided via one or more guides 436, 438. Staple pusher 430 may then engage a first staple via staple engagement surface 440 and a second staple via staple engagement surface 442. An example of a wedge 446 which may be configured to slide within cartridge housing 412 is shown in the perspective view of wedge platform 444 in FIG. 23C. Although a single wedge 446 is shown in the figure extending from platform 444, two offset wedges may be configured into a single platform or two individual wedges may be utilized adjacent and offset to one another.

As mentioned above, cartridge housing 412 may be manipulated into an open and closed position for clamping over the tissue. To control the closure of cartridge housing 412 against anvil 422, a stapler control handle may be used, as shown in the cross-sectional views of the stapler control in FIGS. 24A and 24B. FIG. 24A shows stapler handle housing 450 which may house the tensioning and releasing mechanism for opening and closing cartridge housing 412 relative to anvil 422. Grip 452 may be provided for the user to grasp while manipulating the device during insertion and deployment as well as to help articulate actuation handle 454 for opening and/or closing cartridge housing 412. Actuation handle 454 may be pivotally connected to housing 450 via pivot 458 and to actuation linkage 464 via handle pivot 460. When actuation handle 454 is pulled towards grip 452, handle 44 may rotate about pivot 458 and urge actuation linkage 464 to rotate about handle pivot 460. The opposite end of actuation linkage 464 may be rotatably connected via pivot 462 to a translating slide block 466 contained within housing 450. Alternatively, it may be desirable to configure the fixation assembly with the staple jaws preferentially biased in an open position by placing tension on actuation cable 404 with a spring placed in device handle (not shown). Upon insertion of the staple jaws into the main lumen, the jaws may be retained in a closed position by the inner diameter of the main lumen. Upon reaching the yoke portion, the jaws would be adapted to bias open into clearance slots 254 (252) to slide onto either side of presented tissue. Once the fixation has occurred, the jaws of the fixation assembly may be directed to a closed position by the yoke, and then the device main lumen as the fixation assembly is withdrawn from the patient.

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Slide block **466** may anchor actuation cable **404** thereto via a mechanical anchor **470**, e.g., crimps, clamps, adhesives, etc. An upper surface of slide block **466** may comprise rack **468** having a plurality of gear teeth defined thereon. When actuation handle **454** is pulled and actuation linkage **464** is urged proximally, slide block **466** may be forced proximally within travel guide **480**, as indicated by arrow **488**, to thereby pull actuation cable **404** proximally and thereby force cam **400** to rotate and open the cartridge housing. Simultaneously, while slide block **466** is translated proximally, rack **468** may engage and urge gear **484** to rotate clockwise in the figure, which in turn may force gear **484** to engage and urge rack **474**, which is located on a lower surface of complementary slide block **472**, to translate distally within travel guide **478**, as indicated by arrow **486**.

Complementary slide block **472** may anchor actuation cable **406** thereto via anchor **476** in the same or similar manner as anchor **470**. Actuation cable **406** may be attached to anchor **476** with a retention spring **482** optionally interposed between anchor **476** and slide block **472** to take up any excess slack in the cable **406**. FIG. **24B** shows the handle assembly after actuation handle **454** has been actuated and slide blocks **466**, **472** have been translated within their respective channels **480**, **478** to fully or partially clamp cartridge housing **412** against anvil **422** over the tissue. Once cartridge housing **412** has been clamped over the folded tissue, staple deployment actuator **494** may be rotated or urged to pull staple actuation wires **420** to fire the staples into the tissue. Once staple deployment has been completed, actuation handle **454** may be urged distally to reverse the process described above to open the clamp for removal from the tissue region or for repositioning the staple assembly in another region of the tissue.

The actuation cables **404**, **406** as well as staple actuation wires **420** may each be routed through flexible shaft **456**, which connects handle **450** to stapler assembly **410**. Flexible shaft **456** may be comprised of a tubular member having an outer sheath and an optional inner sheath, either or both of which may be made from any of the polymeric materials described above. The shaft **456** may further utilize braided materials, e.g., superelastic materials such as Nickel-Titanium alloy, integrated throughout to increase column strength and to prevent kinking. Alternatively, shaft **456** may be formed of wire (round or square flat configuration) to enhance compressive and/or tensile strength.

In a further variation, although the tissue approximation device **500** may be configured to be flexible, it may also be desirable to actively or passively curve working body **502** to assist in overall placement of the system within the target organ for optimal presentation of tissue overlap **100** prior to placement of the stapler assembly, as shown in the perspective views of FIGS. **25A** and **25B**. For passive actuation, a curved stylet (not shown) may be placed alongside the actuation rods in the actuation rod channels, or in another available space within the working body **502**, to bias the main body **502** in the curvature provided by the stylet. Working body **502** may be optionally configured to have a bending region **504** located proximally of the pod assembly **512**. This optional bending region **504** may be configured to facilitate bending of a portion of the working body **502** in any number of directions or only in a specified direction, depending upon the desired results.

In addition, as depicted in the detail view of FIG. **25C**, a distal position control **507** may be adapted to fit onto working body **502** via a connector tube **514**. Distal position control **507** may be further adapted to be integrated into handle **34** (as shown in FIG. **1**). Distal position control **507** may comprise a

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base **506**, a lever **508** configured to rotate about pivot **510** located on base **506**, a linkage mechanism **516**, an adjustment assembly **518**, and a curvature linkage **519**. An optional cap or seal **517** may be placed over a proximal end of the base **506** to seal or cover an opening to the main lumen of the working body. In operation, lever **508** may be pivotally mounted to base **506** via linkage mechanism **516**. Depending on the amount of curvature desired in bending region **504**, adjustment assembly **518** can be adjusted, e.g., by rotating the mechanism to adjust tension curvature linkage **519** prior to actuation of lever **508**. FIG. **25A** depicts the assembly **500** in the non-deployed, i.e., a straightened position of working body **502**, while FIG. **25B** depicts full actuation of lever **508** to impart a curvature to the distal end of working body **28**. The curvature of bending region **504** may accordingly be adjusted to any intermediate position depending upon the degree of actuation of lever **508**. Furthermore, although the degree of bending of the distal portion of the assembly **500** relative to a longitudinal axis of working body **502** is shown to be about  $45^\circ$  in this example, other variations may be adjusted to have a maximum bend of a lesser or greater degree depending upon the desired bending. Moreover, other variations may allow for bending of the assembly **500** in either a unidirectional manner or in any other direction, again depending upon the desired results. It is further contemplated that the bending region **504** may occur at a variety of locations along the shaft of working body **502**, such as in the distal or proximal region of the working body or at any point therebetween.

As mentioned above, optional cap or seal **517** may be placed over a proximal end of the base **506** to seal or cover an opening to the main lumen of the working body. FIGS. **25D** and **25E** show perspective and end views, respectively, of a variation of end cap or seal **517** which may be used to cap the handle of FIG. **25C**. End cap **517** may seal the main lumen yet allow passage of devices through the membrane through a small expandable opening **523** covering the main lumen. An optional tab or handle **521** may extend from the cap or seal **517** to facilitate handling of the cover. The cap or seal **517** may be formed from any of the polymeric materials described herein, e.g., silicone.

FIG. **26** shows a variation **520** of how the tissue approximation assembly may be utilized with other devices such as an endoscope **522**. In this example, clearance slots (open region **240**) may function to provide clearance for an endoscope **522**, or other tool, that can be inserted into and advanced through the main lumen **40** of working body **28**. During tissue approximation, endoscope **522** may be advanced distally out of main lumen **40** and advanced past pod assembly **16**. A bending region **524** of endoscope **522** may then be retroflexed to view the results or progress of the tissue approximation and/or fixation using an imaging system **526**, e.g., optical fibers, CCD or CMOS imaging system, etc., positioned within a distal end of the endoscope **522**.

FIG. **27** shows a portion of flexible shaft **456** of the fixation assembly inserted through main lumen **40** of handle **110** in assembly **490**. Handle **110** is partially shown for clarity. As mentioned above, one or several insertion indicators **492** may be defined along a portion of flexible shaft **456** at predetermined positions. These indicators are preferably located near a proximal end of shaft **456** to indicate information to the user. For instance, when shaft **456** is aligned against handle **110** at one particular indicator, this may notify the user when it is safe for stapler assembly **410** to be opened in a patient body, e.g., when cartridge housing **412** is positioned proximally of the tissue between the yoke members. A second indicator defined along shaft **456** may indicate to the user when the second indicator is aligned against handle **110** that it is safe to



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clamp stapler assembly **410** over the tissue, e.g., when stapler assembly **410** is positioned fully over the approximated and folded tissue thereby indicating that the cartridge housing **412** may be clamped against anvil **422** and the tissue for staple deployment. Additional indicators may be defined along shaft **456** to indicate various other information, e.g., positional information such as how deep stapler assembly has been inserted relative to the folder assembly. These examples are merely intended to be illustrative and are not limiting in how indicators defined along the shaft **456** may be utilized.

Once the tissue has been affixed, stapler assembly **410** may be removed from the main lumen of the folder assembly and an endoscopic device may be optionally inserted within the main lumen. The endoscopic device may be outfitted with a visual imaging system, e.g., fiberoptic, CCD, CMOS, etc., to view the tissue region. If necessary, stapler assembly **410**, or some other tool, may be subsequently inserted through the main lumen to perform additional aspects of the procedure, or to complete the procedure with the placement of additional fixation elements.

In describing the system and its components, certain terms have been used for understanding, brevity, and clarity. They are primarily used for descriptive purposes and are intended to be used broadly and construed in the same manner. Having now described the invention and its method of use, it should be appreciated that reasonable mechanical and operational equivalents would be apparent to those skilled in this art. Those variations are considered to be within the equivalence of the claims appended to the specification.

#### Additional Devices and Methods

Another embodiment of a system for tissue approximation and fixation will now be described that includes a vacuum pod integrated with a fixation assembly. The fixation assembly of this embodiment is similar to the fixation assembly **14** described above. Referring to FIG. **28**, a fixation assembly or endoscopic stapler **550** includes a stapler assembly **552** or cartridge assembly connected via a flexible shaft **554** or elongated body having a proximal end and a distal end to a stapler handle **556**. The stapler assembly includes a fixation member having a staple cartridge **558**, within which one or more staples are housed, and an anvil **560** in apposition to staple cartridge used to provide a staple closure surface when tissue to be affixed is adequately positioned between staple cartridge and anvil. An optional smooth rubber tip **562** with a guide wire channel **564** may be attached to the distal end of the staple cartridge. The atraumatic tip **562** prevents injury to tissue when the device is advanced down the esophagus, and the guide wire channel allows the fixation assembly to track down a guide wire. The stapler assembly also includes an acquisition member for acquiring tissue. In one embodiment a vacuum pod **566** is attached or integrated into the staple cartridge **558**, and a vacuum line or tubing (not shown) extends from the vacuum pod, along the shaft **554** and to the handle **556**. It is preferred that the overall insertion diameter of the stapler assembly and flexible shaft plus endoscope is equal to or less than 54 Fr.

With stapler assembly **552** connected at the distal end of flexible shaft **554**, the handle **556** is connected at the proximal end of shaft. The flexible shaft **554** is configured to be curved, and in one embodiment can achieve a 4 inch bend radius with a low application of force. The handle **556** may include a housing and grip **572** in apposition to an actuation handle **574**. In use, the handle **556** allows the surgeon or user to hold and manipulate the fixation assembly **550** with grip **562** while articulating stapler assembly **552** between an open and close configuration via the actuation handle **574**. A lever or staple deployment actuator **570** is also disposed on the handle **556** and is used to deploy staples from the stapler assembly **552**.

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Moreover, the configuration of the handle **556** allows the surgeon or user to articulate the stapler assembly **552**.

In one embodiment, the anvil **558** may be pivotally connected via a pivot **578** to the end of flexible shaft **554** as shown in FIG. **30**. The staple cartridge **558** may be configured to remain stationary relative to the flexible shaft **554** while anvil **560** may be manipulated into an open and closed configuration with respect to flexible shaft and staple cartridge. However, in another embodiment, the staple cartridge may be pivotally connected to the flexible shaft and the anvil remains stationary. In yet another embodiment, both the anvil and the staple cartridge can pivot into an open and closed configuration relative to the flexible shaft. FIG. **30** also shows one embodiment of the fixation assembly having teeth **579** disposed on the surface of the staple cartridge **558** to better grip the acquired tissue. To manipulate the anvil **560** to an open and closed configuration, a circular or disk-shaped cam **580** may be pivotally attached about rotational pivot **582** located on the side of the proximal end of stapler assembly **552**, as best shown in the partial cross-sectional view of FIG. **31**. The cam **580** operates in a similar manner to the cam **400**, which is described in detail above. Actuation wires or cables **584**, **586** may be wound about cam **580** such that when cable **584** is pulled, cam **580** is urged to rotate clock-wise (relative to FIG. **31**) about rotational pivot **582**. Actuation cables **584**, **586** may be manipulated from their proximal ends by the user. As cam **580** is rotated in a clock-wise direction, a portion of staple cartridge **558** may be engaged by the cam thereby forcing the anvil **560** to pivot into an open configuration, as shown in FIG. **30**. One cam may be utilized, as shown; however, an additional cam may also be affixed on the opposite side of stapler assembly **552** such that dual cams are configured to open and close simultaneously in parallel. Alternatively, in the same device, the location of stapler cartridge **558** and anvil **560** may be reversed (e.g. cartridge may be configured to move toward anvil) depending on the location of the desired target and clearance desired.

In one embodiment of the fixation assembly **550**, there are two rows of staple apertures **588** defined over the surface of the staple cartridge **558**, as best shown in FIG. **30**. Staples are deployed through the apertures in a similar manner as described in detail above referring to FIGS. **22A** to **23C**, by pulling a staple actuation wire that in turn moves a wedge in contact with a staple pusher to fire a staple. In this embodiment, the lever or staple deployment actuator **570** is depressed to pull the actuation wire in order to fire the staples from the stapler assembly. Other variations may utilize fewer or greater than two rows of staple apertures. To control the closure of anvil **560** against the staple cartridge **558**, the stapler control handle **556** may be used in the same manner as the handle **450** described in FIGS. **24A** to **24B**. It is noted that in this embodiment of the fixation assembly **550**, it is the anvil that is being moved from an open to a closed position relative to the staple cartridge and the flexible shaft.

Generally, when the fixation assembly **550** is advanced over a guide wire through the guide wire channel **564** of the rubber tip and down the esophagus to the stomach cavity, the stapler assembly **552** is preferably in a closed configuration as shown in FIG. **29**. Further, the fixation assembly may be compatible with the side-by-side insertion of a 8.6 mm diameter flexible endoscope or similar scope. The device will be axially located by referencing external markings on the shaft of the device, or visually by using markings on the head of the stapler assembly **552** relative to the "z-line." In terms of radial location, the device will be rotated and placed while under direct visualization. Once the stapler assembly **552** is in the



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desired position within the stomach cavity for placing a plication along the stomach wall, the guide wire is removed, and the stapler assembly may be articulated into an open configuration as shown in FIG. 30. A vacuum may then be created at the vacuum pod 566 through a vacuum pod opening 576 to acquire a fold of tissue between the staple cartridge 558 and the anvil 560. It is preferred that a vacuum device be used to achieve a vacuum level of about 28 in Hg to about 29.5 in Hg. After the vacuum level has stabilized, the jaws of the stapler assembly 552 are then clamped closed over the tissue and then the staples are deployed into the acquired tissue. Vacuum is then released and the stapler assembly 552 is opened and the device is slightly advanced and rotated to allow for the gastric tissue to pull free from the vacuum pod, or vacuum may be reversed to expel the tissue from the pod. Once the tissue is free, the device is withdrawn and may have the staple cartridge reloaded for another firing if necessary. Multiple plications may be positioned using the fixation assembly 550 anywhere within the stomach cavity or newly created gastric sleeve or pouch.

Another embodiment of a device for tissue acquisition and fixation is shown in FIGS. 32 and 33. FIG. 32 depicts an exploded view of a cross stapler device 600 that is able to place a plication within the stomach wall that is generally perpendicular to the longitudinal body of the stapler device. Stapler device 600 includes a distal frame 602 having a stapler cartridge lumen 604 and a vacuum lumen 606. Near the distal end of the frame 602 is a vacuum opening 608 that is in fluid communication with the vacuum lumen 606. An anvil seat 610 is formed at the distal end of the frame and is in line with, although not in connection with, the staple cartridge lumen 604. A staple cartridge body 612 includes staple pushers 614 at its distal end, cable through holes 616 at its proximal end, and a central hole 618 through the middle of the cartridge body. The staple cartridge body is housed within a cartridge housing 620 having a housing central hole 622 through the middle of the cartridge housing and housing cable through holes 624 that are in line with the through holes 616 of the staple cartridge body. The distal end of the cartridge housing includes an opening (not shown) for the staple pushers 614 to extend through. With the staple cartridge body 612 positioned inside, the cartridge housing 620 is positioned within the staple cartridge lumen 604 of the frame, which also includes a frame central hole 626 that is in-line with the housing central hole 622 and the central hole 618 of the cartridge body. An anvil 628 is secured within the anvil seat 610 with dowel pins 630, however, the anvil may be secured by any other means as well. The anvil is in apposition to the staple pushers 614 and is used to provide a staple closure surface when tissue to be affixed is adequately positioned between staple pushers and anvil. The surfaces of the anvil and the staple pushers each lie in a separate plane that is perpendicular to the longitudinal axis of the device, allowing the cross stapler device to form cross folds or flaps of tissue within the stomach cavity. An optional nose cone 632 may be connected to the distal end of the frame 602, and in one embodiment is partially connected to the anvil seat 610. The nose cone provides an atraumatic tip for the device 600. The stapler cartridge is activated with actuation cables 634, which each include a crimped end or distal end tip 636 that is larger in diameter than the cables. The cables are housed within cable housings 638 and extend from the frame 602 to a proximal end of the cross stapler device 600 to a handle that a user can control. When assembled, the cables 634 are positioned through the housing cable through holes 624 and the cable through holes 616 of the cartridge body 612, and the distal end tips 636 of the cables are secured within a cable block 640. The cable block

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is positioned within the frame 602 through the frame central hole 628, the housing central hole 622, and the central hole 618 of the staple cartridge body 612. In this embodiment, the cable block 640 directs tension from the cables 634 to the frame 602 while loads are being applied to the clamping and stapling elements, i.e., the cartridge body 612 and staple pushers 614.

In use, the cross stapler device 600 is maneuvered down the esophagus to the stomach cavity. As shown in FIG. 32, an optional scope tube adapter 642 may be connected to the proximal end of the frame 602. The scope tube adapter provides a pathway or a railing for an endoscope to be positioned along the side of the cross stapler device 600 for use during a procedure. Once the cross stapler device is in the desired position within the stomach cavity for placing a transverse or horizontal plication along the stomach wall, the vacuum lumen 606 is connected to a vacuum device for achieving a vacuum at the vacuum opening 608, in order to acquire a fold of tissue between the staple pushers 614 and the anvil 628. The cross stapler device 600 is then activated using the cables 634 to first clamp or compress the acquired tissue by pushing the cartridge housing 620 distally. Mechanisms in the handle of the cross stapler device can be used to push the cables 634 and cable housings 638 distally (towards the anvil), which will in turn push the cartridge housing 620 distally through the frame 602. The cables are being held by the cable block 640 to stabilize the position of the frame and the load carrying ability of the cables, and the central holes 618 and 622 of the cartridge body and housing limit the travel of the cable block and therefore the travel of the cartridge housing as well. With the tissue compressed between the cartridge body 620 and the anvil 628, the cables 634 and cable housings 638 are further pushed distally by mechanisms in the handle to drive the cartridge body 612 and staple pushers 614 distally in order to deploy the staples into the acquired tissue. Either a single or a plurality of staples may be deployed from the staple pushers and into the tissue creating a plication. In another embodiment, only one cable and cable housing may be needed to activate the device 600. Further, it would also be possible to pull the cables proximally at the handle and then reverse the direction of the load at the distal frame to push the cartridge housing and cartridge body distally by using a pivot bar, gear arrangement, or other such means known in the art.

After stapling the acquired tissue, the vacuum is then released and the cross stapler device 600 is rotated to allow for the gastric tissue to pull free from the vacuum opening 608. Once the tissue is free, the device is withdrawn and may have the staple cartridge reloaded for another firing if necessary. Multiple plications may be positioned using the cross stapler device 600 anywhere within the stomach cavity or newly created pouch, for example a series of plications may be placed one after the other.

Another embodiment of the cross stapler device, designated 600a, is shown in FIG. 34, where like reference numerals are used for designating like elements. This embodiment includes a mechanical device to acquire targeted tissue. In one embodiment, the mechanical device may include a grasper 644 having a grasper cable 646 and claws or pinchers 648 at the distal end of the cable. Instead of using a vacuum to acquire tissue, the grasper is extended with claws opened as shown in FIG. 34, and then the claws are closed to grab and pull tissue between the staple pushers 614 and anvil 618. The frame 602 of this embodiment has been modified to accommodate the grasper. For instance, there is a ramp 650 formed near the distal end of the frame 602 that creates a gap 652 in the anvil. The ramp helps direct the grasper towards the stomach tissue. In this embodiment, the compression and fixation

of the acquired tissue are activated in the same manner as described above with reference to the cross stapler device 600.

The fixation assembly or endoscopic stapler 550 is a device intended to facilitate transoral stomach stapling procedures, and can be used as a device for performing a secondary step in a gastric sleeve or pouch formation procedure. For example, the fixation assembly 550 can be used to form one or more plications in the distal end of a formed gastric sleeve to narrow the outlet of the gastric sleeve. The fixation assembly can also be used to reinforce the gastric sleeve, and in some situations close a stoma or fistula created by a gastric sleeve. Use of the fixation assembly of this embodiment as a secondary procedure can occur immediately following the primary procedure, or can be carried out at a later date when, for example, the stomach has remodeled itself due to overeating by the patient or other forces that operate on the plications once they are placed.

The primary gastric sleeves can be created using the fixation assembly 550, or can be created by another device, such as the one disclosed in U.S. Ser. No. 10/797,439 ("the '439 application"), titled "Devices And Methods For Placement Of Partitions Within A Hollow Body Organ." The '439 application is hereby incorporated by reference in its entirety. The tissue acquisition and fixation device disclosed in the '439 application (referred to as "the '439 device") is used to create longitudinal dual fold plications within the stomach wall, by acquiring two folds of tissue and then stapling the folds together. One method of narrowing a distal stoma with the fixation assembly 550 will now be described with reference to cross sectional views shown in FIGS. 35 through 42.

As shown in FIG. 35, the '439 device 660 is placed within the stomach cavity SC with an endoscope 662 positioned along the '439 device to provide visualization of the procedure. The '439 device includes a cartridge member 664 placed longitudinally in apposition to an anvil member 666, and an optional septum 668 is removably positioned between the cartridge member and the anvil member. Vacuum ports 670 can be disposed within the cartridge member 664 and the anvil member 666 to each acquire tissue. Once the '439 device is in position within the stomach cavity, the jaws or the cartridge member and the anvil member are opened as shown in FIG. 35. A vacuum is then created at the vacuum ports 670 to each acquire a separate fold of tissue 672 as shown in FIG. 36. The optional septum helps create the dual folds of tissue. Once the tissue is stabilized within the vacuum ports, the septum 668 is removed as shown in FIG. 37. Referring now to FIG. 38, with the septum removed, the jaws (cartridge member and anvil member) of the '439 device are clamped together and staples are fired out of the cartridge member to secure the dual fold of tissue. After forming the longitudinal plication 676 (see FIG. 43) the '439 device is removed from the stomach cavity leaving the endoscope 662 within the newly formed pouch of tissue as shown in FIG. 39.

As shown in FIG. 40, the fixation assembly 550 is advanced down the esophagus alongside the endoscope 662 so that the stapler assembly 552 is near the distal stoma 678 (see FIG. 43) created by the longitudinal plication. Next, the jaws of the fixation assembly are opened, in one embodiment the anvil 560 is rotated away from the staple cartridge 558, and a vacuum is applied to the vacuum pod 566 to acquire tissue. Referring now to FIG. 41, with a fold of tissue 680 positioned between the staple cartridge 558 and the anvil 560, the anvil is clamped down against the staple cartridge, and staples are fired from the staple cartridge to secure the single fold of tissue. The fixation assembly 550 and endoscope 662 are then removed from the stomach cavity, leaving the geometry

shown in FIG. 42, which is a cross sectional view taken along line 42-42 of FIG. 43. FIG. 43 is an illustrative view of the stomach cavity showing the longitudinal plication 676 and the single fold of tissue 680 created by the fixation assembly 550 to decrease the diameter of the distal stoma 678. Additional plications may be placed within or near the pouch at the outlet stoma either circumferentially or longitudinally with respect to the initially placed plication.

In another embodiment, the fixation assembly 550 could also be used to reduce or reinforce multiple orifices defined within the stomach cavity. Multiple plications or fastening lines may be disposed within the stomach cavity to divide the stomach cavity as disclosed in U.S. Ser. No. 10/188,547 ("the '547 application"), titled "Method and Device For Use In Tissue Approximation And Fixation." The '547 application is hereby incorporated by reference in its entirety. The plications or fastening lines disclose in the '547 application could be created using the '439 device or the fixation assembly 550. When placing multiple plications within the stomach cavity, distal stomas 678 formed by the longitudinal plications 676 may need to be narrowed. FIGS. 44 and 45 show the stomach cavity with multiple longitudinal plications 676 and a single fold of tissue 680 formed using the fixation assembly 550 near each of the distal stomas 678 to reduce the size or diameter of the stomas. The procedure will be very similar to the one described above with reference to FIGS. 35 through 43. The fixation assembly 550 can be used to form the single fold of tissue 680 immediately after the plications are created, or the procedure to reduce the distal stomas may occur at any later time. Also, multiple single folds can be created with the fixation assembly around the created pouch or stoma to reduce its diameter even further. As previously stated, the fixation assembly may also be used to reinforce the plications by acquiring the plication and forming a staple line over the previous staple line forming the original longitudinal plication.

Stomas may also be created within the stomach cavity with mechanical devices, such as anchors or bands that are attached to the inner surface of the stomach cavity and then cinched together. For instance, U.S. Ser. No. 11/056,327 ("the '327 application"), titled "Method and Devices For Reducing Hollow Organ Volume," discloses attaching anchors or staples to the stomach wall and then cinching them together with a tension member attached to each anchor or staple to form a narrowing of the stomach cavity. Also, U.S. Ser. No. 11/067,598 ("the '598 application"), titled "Methods and Devices For Reducing Hollow Organ Volume," discloses attaching intragastric bands to the inner wall of the stomach and then cinching or decreasing the diameter of the band to form a stoma within the stomach cavity. The '327 and '598 applications are hereby incorporated by reference in its entirety.

FIG. 46 shows a stoma 682 created within the stomach cavity SC with an intragastric band 684. After the intragastric band has been secured to the stomach wall and cinched to form the stoma, the fixation assembly 550 or the cross stapler device 600 may then be advanced to the stomach cavity and positioned to place single folds of tissue 680 around the stoma to decrease the diameter of the stoma. The fixation assembly 550 or the cross stapler device 600 will gather portions of the intragastric band as well as the stomach wall, and therefore, the band will further be secured to the stomach wall. Multiple plications can be formed around the circumference of the intragastric band as desired to reduce the size of the stoma. The fixation assembly or the cross stapler device can be used to reduce a stoma created by any mechanism known in the art that creates stomas within the stomach cavity, such as the

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cinched anchors disclosed in the '327 application. Also, the fixation assembly or cross stapler device can be used to further secure the mechanical device to the stomach wall.

The fixation assembly 550 can also be used to correct a primary procedure. For example, if a longitudinal plication 676 is placed within the stomach cavity, as discussed above with reference to the '439 device, in a lower position from the gastroesophageal junction ("GEJ") than desired, a proximal stoma 686 may be created as shown in FIG. 47. Usually it is desired that the proximal stoma be completely closed to prevent food from entering there through. In this situation, the fixation assembly 550 may be used to acquire tissue at the proximal stoma 686 and fix the acquired tissue together to close the proximal stoma. FIG. 48 shows the proximal stoma 686 closed by a single fold of tissue 680 that was formed with the fixation assembly 550. In this procedure, the fixation assembly may be reloaded with staples and then used to form a plication or single fold of tissue near the distal stoma to reduce its diameter or overall size.

In another example, the longitudinal plication 676, placed using the '439 device as described above, may be at an angle away from the lesser curve LC of the stomach creating a relatively large distal stoma 676 as shown in FIG. 49. To reduce the size of the distal stoma in this example, the fixation assembly 550 can be used to place multiple plications around the circumference of the distal stoma. FIG. 50A shows a cross-sectional view taken along line 50-50 of FIG. 49, after two single folds of tissue 680 have been created at the distal stoma thereby reducing its diameter. It would also be possible to place more single folds around the stoma depending on the desired diameter. In another embodiment, the larger than desired stoma shown in FIG. 49 may also be reduced by using the '439 device to place a dual fold in the middle of the stoma by acquiring and fixing tissue from the anterior and posterior walls of the stomach. The '439 device could be re-deployed to the stomach cavity and positioned at the distal stoma 678 to acquire and fix a dual fold of tissue 674 within the distal stoma as shown in FIG. 50B. Due to the placement of the dual fold in this embodiment, two smaller outlets 688 are formed at the distal stoma 678.

The cross stapler device 600 is also a device intended to facilitate transoral stomach stapling procedures, and can be used as a device for performing a secondary step in a gastric sleeve formation procedure. For example, the cross stapler device 600 can be used to form one or more cross-folds within a formed gastric sleeve to narrow the outlet of the gastric sleeve, and/or to act like a valve within the gastric sleeve. Use of the cross stapler device as a secondary procedure can occur immediately following the primary procedure, or can be carried out at a later date when, for example, the stomach has remodeled itself due to overeating by the patient or other forces acting on the plications.

As described above, the '439 device can be used to form a longitudinal plication 676 within the stomach cavity SC to create a gastric sleeve or pouch with a distal stoma or outlet 678. Referring now to FIG. 51, after forming the gastric sleeve with the '439 device, or any other device, the cross stapler device 600 can be advanced down the esophagus and positioned within the gastric sleeve at a desired location for forming a cross fold or flap of tissue 690. Once in position, the cross stapler device can acquire tissue from the lesser curve LC of the stomach, either with a vacuum pod or a grasper, depending on the embodiment. After acquiring the tissue between the staple pushers 614 and the anvil 628, the cross stapler device is actuated to secure the cross fold of tissue with a plurality of staples. The cross fold of tissue is a fold of tissue that is generally perpendicular to the longitudinal pli-

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cation 676, and acts similar to a flap of a valve. A cross-sectional view taken along line 52-52 of FIG. 51 is shown in FIG. 52 with the cross stapler device removed for clarity. It is also contemplated that the cross stapler device can form a cross fold of tissue on the longitudinal plication 676 as well, or on the anterior or posterior wall of the stomach. Further, the cross stapler device can be used to place two cross folds of tissue opposite of each other in the gastric sleeve as shown in FIG. 53 to form a valve-like structure.

In another embodiment, the '439 device could be used to over-staple an existing dual fold of tissue at the distal stoma of a gastric sleeve to reinforce the dual fold. Reinforcing the staple line near the distal stoma may be desired because over time the distal stoma or outlet could begin to stretch out and/or the staples could begin to loosen as well. FIG. 54 depicts an existing longitudinal plication 676 within the stomach cavity, and the '439 device 660 being positioned near the distal stoma to reacquire the dual fold of tissue and place another staple line over the preexisting staple line. When reacquire the dual fold of tissue, the '439 device will not include the optional septum. It has been contemplated that the '439 device could include only a single vacuum port disposed between the cartridge member and anvil instead of having a vacuum port in each of the cartridge member and anvil. The '439 device with a single vacuum port could more easily reacquire the dual fold of tissue already secured together to form the longitudinal plication.

In one embodiment, a laparoscopically placed band 692 (such as the silastic band used in a VBG procedure) could be positioned around the outer surface of the stomach to form an outlet stoma 694 after a gastric sleeve has been formed within the stomach cavity by placing a longitudinal plication 676 within the stomach cavity as shown in FIG. 55. The longitudinal plication could be placed transorally with the '439 device, and then the band 692 could be placed laparoscopically around the stomach at the distal outlet of the pouch or sleeve created by plication 676. This embodiment reduces the volume of the stomach cavity. Such a band is used in a procedure known in the art as a vertical, banded gastroplasty ("VBG"), and is shown in FIG. 2 of U.S. Pat. No. 6,773,440, which is hereby incorporated by reference. Such an externally/laparoscopically placed band may also be formed of polyester, PTFE, silicone impregnated mesh, silicone or other biocompatible materials that limit erosion and promote tissue in-growth and healing.

Other methods could also be used to further reduce the diameter of a distal stoma of a gastric sleeve. In one embodiment, a fabric/mesh band 696 having a tensioning member that is sutured to the band in a purse-string configuration can be attached to the stomach wall near the distal stoma 678 of the gastric sleeve as shown in FIG. 56. The fabric/mesh band, and other intragastric bands that may be used as well, are disclosed in the '598 application, which has already been incorporated by reference. FIG. 56 shows the longitudinal plication 676 placed within the stomach cavity and the fabric/mesh band attached near the distal stoma 678 and cinched to reduce the diameter of the stomach. The fabric/mesh band may be attached to the stomach wall with sutures, staples, anchors, hooks, rivets, adhesives, or any other means. In one embodiment, the cross stapler device 600 is used to secure the fabric/band to the stomach wall. Further, the cross stapler device could be used to secure other intragastric bands or pledget that are disclosed in the '598 application. In another embodiment, the method of cinching together staples or anchors in the stomach cavity disclosed in the '327 applica-

tion, which has already been incorporated by reference, could also be used within the gastric sleeve to reduce the diameter of a distal stoma.

In another embodiment, a stent, such as a nitinol stent, could be secured within the gastric sleeve near the distal stoma. The stent would be positioned similar to the fabric/mesh band as shown in FIG. 56. In use, a stent having an expanded diameter that is larger than the diameter of the distal stoma may be chosen, so that the stent will be secured within the gastric sleeve by friction. The stent would provide a surface for tissue to grow around, thereby reducing the diameter of the distal stoma. In another embodiment, a stent may be secured near the distal stoma that is biased to a closed position, so that once secured within the gastric sleeve, the stent will reduce the diameter of the distal stoma. In this last embodiment, the stent may be secured to the gastric sleeve with sutures, staples, anchors, or the like. In yet another embodiment, a valve could be placed near the distal stoma of the gastric sleeve. The valve would block incoming food until the pressure of the built up food would force the valve open. There are several valves disclosed in U.S. Ser. No. 11/091,023 ("the '023 application"), titled "Systems And Methods For Treating Obesity," that can be secured within the gastric sleeve. The '023 application is hereby incorporated by reference in its entirety.

Another method for narrowing the distal stoma of a gastric sleeve would be to place a surgical clip at the distal stoma. One example of a surgical clip is disclosed in U.S. Pat. No. 6,641,593 ("the '593 patent"), titled "Tissue Connector Apparatus And Methods," and is hereby incorporated by reference in its entirety. Surgical clips, such as the one described in the '593 patent may be formed of a deformable wire made of a shape memory alloy like nitinol. Once attached near the distal stoma 678 and released, the surgical clip will begin to self close and narrow the stoma as shown in FIG. 57. The surgical clip may be secured near the distal stoma with sutures, staples, anchors, or the like.

In yet another embodiment for reducing the diameter of the distal stoma, a plurality of magnets may be implanted into the tissue around the distal stoma 678 to close the distal stoma until the magnetic force is overcome by gastric pressure due to the presence of food filling the gastric sleeve. In one embodiment, a first magnet 700 may be secured or implanted within the anterior wall of the stomach cavity and a second magnet 702 may be secured or implanted within the posterior wall of the stomach cavity as shown in FIGS. 58 and 59. One method of securing the magnets to the stomach wall would be to place them in a closed polyester or PTFE sleeve or enclose them with a coating that is sutured or stapled to the stomach wall. Another method of securing the magnets, would be to form a hole within the lining of the stomach and then position the magnet into the stomach wall. As shown in FIG. 59, the magnets will attract one another to close the distal stoma 678. As the patient eats and food builds up within the gastric sleeve, the pressure of the built up food will force the magnets apart from one another to allow the food to pass. The magnets will not completely close the distal stoma, and therefore liquids will be allowed to pass through smaller openings 704 at the distal stoma that are not sealed by the magnets.

Another embodiment of reducing the diameter near the distal stoma of the gastric sleeve involves delivering energy scarification or ablation using RF, ultrasound, HIFU, microwave, laser or other energy to induce tissue shrinkage or a desired amount of stricture to reduce the distal stoma. Embodiments for using ablation and remodeling tissue are disclosed in U.S. Pat. No. 6,866,663, titled "Method For Treating A Sphincter," which is hereby incorporated by ref-

erence. As shown in FIG. 60, a catheter 706 having a distal tip 708 and an energy delivery device 710 has been introduced down the esophagus to the stomach cavity. The energy delivery device has been extended from the distal tip of the catheter and positioned a certain distance within the stomach tissue. In this position, energy, such as those listed above, may be applied through the energy delivery device to the stomach tissue near the distal stoma 678 of the gastric sleeve formed by the longitudinal plication 676. The catheter may be rotated within the gastric sleeve and the energy delivery device repositioned within the stomach cavity as many times as needed until the desired diameter at the distal stoma is achieved. FIG. 61 shows the catheter 706 removed and a reduced diameter near the distal stoma caused by the shrinkage of tissue near the distal stoma. In other embodiments, the catheter could be used to deliver cryogenic energy, caustic agent, or other chemical to cause tissue shrinkage near the distal stoma.

In another embodiment, the diameter of the distal stoma may be reduced by introducing a bulking agent into the nearby tissue. A method of introducing a bulking agent into the stomach tissue is disclosed in U.S. Ser. No. 10/386,241 ("the '241 application"), titled "Method For Treating Morbid Obesity," which is hereby incorporated by reference. As shown in FIG. 62, a catheter 712 having a distal tip 714 is introduced down the esophagus to the gastric sleeve formed by the longitudinal plication 676. Once in position an ejection needle 716 is extended from the distal tip of the catheter and into the stomach tissue. A bulking agent is then ejected from the ejection needle and into the stomach tissue. The catheter may be rotated and the ejection needle repositioned within another area of the stomach tissue to eject more of the bulking agent until the desired diameter of the distal stoma is achieved. Preferred bulking agents are any of those solutions disclosed in the '241 application, and include collagen, silicone, and other biocompatible polymers. Additional bulking agents that may be injected into the tissue surrounding the distal stoma or outlet include tissue cells, and injectable embolization devices, such as coils and beads. FIG. 63 shows a bulge of tissue 718 created by injecting a bulking agent into the tissue near the distal stoma 678 to reduce its diameter.

In another embodiment, the distal stoma of the gastric sleeve could be reduced by laparoscopic placement of an external single or dual fold of tissue near the distal stoma. A single fold may be placed on the external surface of the stomach using the fixation assembly 550, and a dual fold of tissue may be placed using the '439 device. FIG. 64 shows a cross-sectional view of the stomach cavity taken near the distal stoma, with an external single fold of tissue 720 placed along the lesser curve of the stomach near the outlet of the gastric sleeve. During the procedure, an endoscope could be used to help position the fixation assembly or other stapler device on the external surface of the stomach where the distal stoma is located.

Although the above embodiments teach placing a restriction near the distal stoma of the gastric sleeve, by placing additional folds, devices (intragastric band and clips), or by restructuring the stomach tissue (ablation and ejection of bulking agents), these restrictions can be placed anywhere along the gastric sleeve. Further, multiple restrictions can be created or placed along the gastric sleeve in combination to create a labyrinth or series of restrictions.

In describing the system and its components, certain terms have been used for understanding, brevity, and clarity. They are primarily used for descriptive purposes and are intended to be used broadly and construed in the same manner. Having now described the invention and its method of use, it should be appreciated that reasonable mechanical and operational equivalents would be apparent to those skilled in this art.

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Those variations are considered to be within the equivalence of the claims appended to the specification.

We claim:

1. A surgical method, comprising:
  - translumenally advancing a flexible elongate shaft having a vacuum chamber at a distal end thereof into a stomach of a patient;
  - applying a vacuum force through the vacuum chamber to adhere stomach tissue to the vacuum chamber; and
  - with the tissue adhered to the vacuum chamber, moving the vacuum chamber relative to the shaft in a direction transverse to a longitudinal axis of the shaft to form a fold in the stomach tissue.
2. The method of claim 1, wherein the vacuum chamber is located in a pod at the distal end of the shaft, and moving the vacuum chamber relative to the shaft comprises moving the pod relative to the shaft in the direction transverse to the longitudinal axis of the shaft.
3. The method of claim 2, wherein, when the shaft is advanced, when the vacuum force is applied, and after the pod is moved relative to the shaft in the direction transverse to the longitudinal axis of the shaft, the longitudinal axis of the shaft and a longitudinal axis of the pod are substantially parallel.
4. The method of claim 1, wherein translumenally advancing the shaft comprises advancing the shaft along the longitudinal axis thereof.
5. The method of claim 1, further comprising, with the tissue adhered to the vacuum chamber, applying a fastener to the tissue fold to affix the tissue fold.
6. A surgical method, comprising:
  - translumenally advancing a flexible elongate shaft having a pod extending from a distal end thereof into a stomach of a patient such that the pod leads the shaft into the stomach;
  - applying a vacuum force via the pod to adhere stomach tissue to the pod; with the tissue adhered to the pod, moving the pod radially relative to the shaft to form a fold in the stomach tissue; and
  - applying a fastener to the tissue fold to affix the tissue fold.
7. The method of claim 6, wherein moving the pod radially relative to the shaft comprises moving the pod perpendicular to a longitudinal axis of the shaft.
8. A surgical device, comprising:
  - a flexible elongate shaft configured to be translumenally advanced into a body of a patient;
  - a pod assembly at a distal end of the shaft, the pod assembly being configured to apply a vacuum force to tissue of the patient, and the pod assembly being configured to move relative to the shaft between a first configuration and a second configuration, the pod assembly in the second configuration being moved relative to the shaft in a direction transverse to a longitudinal axis of the shaft such that the pod assembly is a greater radial distance away from the longitudinal axis of the shaft than when the pod assembly is in the first configuration; and
  - an actuator extending along the shaft and being configured to be actuated to selectively move the pod assembly between the first configuration and the second configuration;
- wherein the pod assembly includes opposed first and second pod members;
- wherein when the pod assembly is in the first configuration, the first pod member is at a first radial position relative to the longitudinal axis of the shaft and the second pod member is at a second radial position relative to the longitudinal axis of the shaft; and

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wherein when the pod assembly is in the second configuration, the first pod member is at a third radial position relative to the longitudinal axis of the shaft and the second pod member remains at the second radial position relative to the longitudinal axis of the shaft, the third radial position being farther away from the longitudinal axis than the first radial position.

9. The device of claim 8, wherein the pod assembly has a vacuum chamber formed therein that is configured to have the tissue adhered thereto.

10. The device of claim 8, wherein when the pod assembly is in the first configuration and in the second configuration, a longitudinal axis of the pod assembly is substantially parallel to the longitudinal axis of the shaft.

11. The device of claim 8, wherein the pod is configured to move relative to the shaft between the second configuration and a third configuration; and

when the pod assembly is in the third configuration, the first pod member remains at a third radial position and the second pod member is at a fourth radial position relative to the longitudinal axis of the shaft, the fourth radial position being farther away from the longitudinal axis than the second radial position.

12. The device of claim 8, wherein the pod assembly includes a chamber formed therein, the vacuum force being configured to draw the tissue into the chamber.

13. The device of claim 8, wherein the actuator includes a rod extending along the shaft.

14. A surgical method using a device comprising a flexible elongate shaft configured to be translumenally advanced into a body of a patient, and a pod assembly at a distal end of the shaft, the pod assembly being configured to apply a vacuum force to tissue of the patient, and the pod assembly being configured to move relative to the shaft between a first configuration and a second configuration, the pod assembly in the second configuration being moved relative to the shaft in a direction transverse to a longitudinal axis of the shaft such that the pod assembly is a greater radial distance away from the longitudinal axis of the shaft than when the pod assembly is in the first configuration, the method comprising:

advancing the distal end of the shaft into the body of the patient, wherein advancing the distal end of the shaft includes advancing the distal end of the shaft into a stomach of the patient;

positioning the pod assembly adjacent to the tissue of the patient;

applying the vacuum force; and

moving the pod assembly from the first configuration to the second configuration, thereby forming a fold in the tissue;

wherein the pod assembly includes opposed first and second pod members;

wherein when the pod assembly is in the first configuration, the first pod member is at a first radial position relative to the longitudinal axis of the shaft and the second pod member is at a second radial position relative to the longitudinal axis of the shaft; and

wherein when the pod assembly is in the second configuration the first pod member is at a third radial position relative to the longitudinal axis of the shaft and the second pod member remains at the second radial position relative to the longitudinal axis of the shaft, the third radial position being farther away from the longitudinal axis than the first radial position.

15. The method of claim 14, further comprising moving the pod assembly from the second configuration to a third configuration;

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wherein when the pod assembly is in the third configuration, the first pod member remains at a third radial position and the second pod member is at a fourth radial position relative to the longitudinal axis of the shaft, the fourth radial position being farther away from the longitudinal axis than the second radial position.

**16.** A surgical method using a device comprising a flexible elongate shaft configured to be translumenally advanced into a body of a patient, and a pod assembly at a distal end of the shaft, the pod assembly being configured to apply a vacuum force to a tissue of the patient, and the pod assembly being configured to move relative to the shaft between a first configuration and a second configuration, the pod assembly in the second configuration being moved relative to the shaft in a direction transverse to a longitudinal axis of the shaft such that the pod assembly is a greater radial distance away from the longitudinal axis of the shaft than when the pod assembly is a greater radial distance away from the longitudinal axis of the shaft than when the pod assembly is in the first configuration, the method comprising:

advancing the distal end of the shaft into the body of the patient, wherein advancing the distal end of the shaft includes translumenally advancing the distal end of the shaft into the body of the patient;

positioning the pod assembly adjacent to the tissue of the patient;

applying the vacuum force; and

moving the pod assembly from the first configuration to the second configuration, thereby forming a fold in the tissue;

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wherein the pod assembly includes opposed first and second pod members;

wherein when the pod assembly is in the first configuration, the first pod member is at a first radial position relative to the longitudinal axis of the shaft and the second pod member is at a second radial position relative to the longitudinal axis of the shaft; and

wherein when the pod assembly is in the second configuration, the first pod member is at a third radial position relative to the longitudinal axis of the shaft and the second pod member remains at the second radial position relative to the longitudinal axis of the shaft, the third radial position being farther away from the longitudinal axis than the first radial position.

**17.** The method of claim **16**, wherein advancing the distal end of the shaft includes advancing the distal end of the shaft into a stomach of the patient.

**18.** The method of claim **16**, further comprising moving the pod assembly from the second configuration to a third configuration;

wherein when the pod assembly is in the third configuration, the first pod member remains at a third radial position and the second pod member is at a fourth radial position relative to the longitudinal axis of the shaft, the fourth radial position being farther away from the longitudinal axis than the second radial position.

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